

Wisconsin
Chapter HFS 157- Radiation Protection
Regulatory Guide

July, 2003

**Guidance for Academic, Research and
Development, and Other Licenses of
Limited Scope**

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PPH 45046 (07/03)

EXECUTIVE SUMMARY

Wisconsin Regulatory Guides (WISREGS) are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of **Wisconsin Administrative Code, Chapter HFS 157 ‘Radiation Protection’** to delineate techniques used by the Department of Health and Family Services (DHFS) staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants or licensees. WISREGS are not substitutes for **Chapter HFS 157 ‘Radiation Protection’**, therefore compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Department of Health and Family Services (DHFS), Radiation Protection Section to determine if a radiation protection program meets the current rule and protects health and safety.

Comments and suggestions for improvements in this WISREG are encouraged. This WISREG will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

Comments should be sent to **Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison, WI 53701-2659**.

To request copies of this guide (which may be reproduced) call DHFS, Radiation Protection Section at (608) 267-4797 or for electronic copy go to our web site at:

http://www.dhfs.state.wi.us/dph_beh/RadioactiveMat/IndexRM.htm.

This WISREG ‘*Guidance for Academic, Research and Development, and Other Licenses of Limited Scope*’ has been developed to streamline the application process for Academic, Research and Development (R&D), and Other Licenses of Limited Scope. DPH form 45016 ‘*Application for Radioactive Material License for Academic, Research and Development and Other Licenses of Limited Scope*’ is located in **Appendix A** of this guide.

Appendices C through T provide examples, models and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **HFS 157.10** for Academic, Research and Development (R&D), and Other Licenses of Limited Scope.

In summary, the applicant will need to perform the following for submitting an Academic, Research & Development, or Other Licenses of Limited Scope license:

- Use this regulatory guide to prepare the application, DPH form 45016, '*Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope*' (**Appendix A**);
- Complete the application, DPH form 45016, '*Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope*' (**Appendix A**). See 'Contents of Application' of this guide for additional information.
- Include any additional attachments:
 - All supplemental pages should be on 8 ½" x 11" paper,
 - Please identify all attachments with the applicant's name and license number (if a renewal);
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit an original signed application along with attachments (if any) and if possible a copy on a diskette or CD (Microsoft Word is preferred);
- Submit the application fee; and
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

If you have any questions about the application process please contact DHFS Radiation Protection Section at (608) 267-4797.

CONTENTS

Executive Summary	2
Contents.....	4
List of Figures	5
List of Tables	5
List of Appendices	6
Abbreviations	7
Purpose of WISREG	9
Who Regulates at Federal Facilities in Wisconsin	12
Management Responsibility	14
Applicable Rule	15
How to File	16
Where to File	17
License Fees	18
Contents of Application	
Item 1 Type of Application	19
Item 2 Name and Mailing Address of Applicant	19
Item 3 Person to Contact Regarding Application	21
Item 4 Address(es) Where Radioactive Material Will Be Used Or Possessed	21
Radiation Safety Officer and Authorized Users	
Item 5 Radiation Safety Officer (RSO).....	23
Item 6 Authorized Users (AU).....	25
Item 7 Training For Individuals Working in or Frequenting Restricted Areas	27
Radioactive Material	
Item 8 Radioactive Material	28
Facilities and Equipment	
Item 9 Facilities and Equipment.....	37
Radiation Protection Program	
Item 10 Radiation Protection Program	39
Item 10.1 Audit Program.....	39
Item 10.2 Radiation Monitoring Instruments	40
Item 10.3 Material Receipt and Accountability	43
Item 10.4 Occupational Dose	49
Item 10.5 Public Dose	52
Item 10.6 Safe Use of Radionuclides and Emergency Procedures	54
Item 10.7 Surveys.....	59
Item 10.8 Transportation	63
Item 10.9 Minimization of Contamination	64
Item 10.10 Termination of Activities	65
Item 11 Waste Management	67
Fees and Certification	
Item 12 License Fees	72
Item 13 Certification	73
Appendices	75

FIGURES

Figure 1	U.S. Map Location of NRC Offices and Agreement States	13
Figure 2	Location of Use	22
Figure 3	RSO Responsibilities	24
Figure 4	Authorized User	26
Figure 5	Methods of Certification of Financial Assurance For Decommissioning	35
Figure 6	Types of Records That Must Be Maintained For Decommissioning	36
Figure 7	Examples of Portable Instruments Used in Laboratory Setting	42
Figure 8	Material Receipt and Accountability	45
Figure 9	Annual Dose Limits For Occupationally Exposed Individuals	50
Figure 10	Calculating Public Dose	53
Figure 11	Use of Appropriate Shielding	55
Figure 12	Proper Handling of Incident	58
Figure 13	Types of Surveys	59
Figure 14	Personnel Surveys	60
Figure 15	Storage of Food and Drink.....	146
Figure 16	Laboratory Layout	160

TABLES

Table 1	Who Regulates the Activity	12
Table 2	Types of Radioactive Material	29
Table 3	Sample Format for Providing Information About Requested Radioisotopes	33
Table 4	Commonly Used Unsealed Licensed Material Requiring Financial Assurance & Decommissioning Funding Plan	35
Table 5	Package Monitoring Requirements	45
Table 6	Record Maintenance	48
Table 7	Isotopes With Half-lives Greater Than or Equal to 120 Days	90
Table 8	Sample Worksheet of Determining Need for a Decommissioning Funding Plan or Financial Assurance.....	91
Table 9	Typical Survey Instruments	127
Table 10	Standard Occupancy Factors	142
Table 11	Suggested Contamination Survey Frequency	156
Table 12	Acceptable Surface Contamination Levels for Equipment	157
Table 13	Screening Values for Building Surface Contamination	158

APPENDICES

Appendix A	DPH form 45016 ‘ <i>Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope</i> ’	75
Appendix B	DPH form 45007 ‘ <i>Certificate of Disposition of Materials</i> ’	76
Appendix C	Reserved	77
Appendix D	Gas Chromatography Device	78
Appendix E	Information Needed for Transfer of Control Application	85
Appendix F	Reserved	88
Appendix G	Guidance on Decommissioning Funding Plan and Financial Assurance	89
Appendix H	Considerations for Laboratory Animal and Veterinary Medical Uses	92
Appendix I	Radiation Safety Officer Duties and Responsibilities	104
Appendix J	Radiation Safety Training Topics	107
Appendix K	Facilities and Equipment Considerations	112
Appendix L	Sample Audit Program	116
Appendix M	Radiation Monitoring Instruments Specifications, Survey Instrument and Air Sampler Calibration Program.	126
Appendix N	Material Receipt and Accountability	134
Appendix O	Public Dose	139
Appendix P	General Topics for Safe Use of Radioisotopes and Model Emergency Procedures ..	144
Appendix Q	Radiation Safety Survey Topics	153
Appendix R	Leak Test Procedures	166
Appendix S	Transportation	169
Appendix T	Waste Management Procedures	179

ABBREVIATIONS

ALARA	As low as is reasonably achievable
ALI	Annual Limit of Intake
ANSI	American National Standards Institute
ARDL	Academic, Research and Development, and other Licenses
AU	Authorized user
bkg	Background
Bq	Becquerel
CDE	Committed Dose Equivalent
CEDE	Committed Effective Dose Equivalent
CD-ROM	Compact disk-read only memory
CFR	Code of Federal Regulations
Ci	Curie
cpm	Counts per minute
DAC	Derived Air Concentration
DCF	Dose Conversion Factor
DDE	Deep Dose Equivalent
DFP	Decommissioning Funding Plan
DHFS	Wisconsin Department of Health and Family Services
DIS	Decay-in-storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	Disintegrations per minute
dps	Disintegrations per second
EDE	Effective Dose Equivalent
EPA	U.S. Environmental Protection Agency
F/A	Financial Assurance
FR	Federal Register
GBq	Gigabecquerel
GC	Gas chromatograph
G-M	Geiger-Mueller
Gy	Gray
IN	Information Notice
LLW	Low Level Radioactive Waste
LSA	Low Specific Activity
LSC	Liquid Scintillation Counter
MBq	Megabecquerel
mCi	Millicurie
mGy	Milligray
ml	Milliliter
mR	Milliroentgen
mrem	Millirem
mSv	Millisievert
mCi	Microcurie
mR	Microroentgen
NaI	Sodium iodide
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission

NVLAP	National Voluntary Laboratory Accreditation Program
OSL	Optical Stimulated Luminescent Dosimeters
R	Roentgen
RG	Regulatory Guide
RQ	Reportable Quantities
RSO	Radiation Safety Officer
SDE	Shallow Dose Equivalent
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	Sealed Source and Device
std	Standard
Sv	Sievert
TEDE	Total effective dose equivalent
TI	Transportation Index
TLD	Thermoluminescence dosimeters
TODE	Total Organ Dose Equivalent
UN	United Nations

PURPOSE OF WISREG

This WISREG provides guidance to an applicant in preparing an Academic, Research and Development and Other Licenses of Limited Scope (ARDL) application including gas chromatography devices (GC). This WISREG also provides DHFS criteria for evaluating the license application. It is not intended to address licenses of broad scope, licenses for manufacturing and distribution of radioactive material, or licenses for the use of source, or special nuclear material.

This guide is designed to be used by applicants for a license (not of broad scope) issued by DHFS that is characterized by a listing of the following specific items:

- Radionuclides;
- Chemical/physical form;
- Possession Limits;
- Radiation Safety Officer;
- Authorized Users; and
- Authorized locations.

Radioactive material, as defined in **HFS 157.03**, is used for a variety of purposes in research, industry, and other fields. The following are typical uses:

- In vivo studies (labeling cells, studies involving animals, excluding humans);
- In vitro studies;
- Analytical work/studies, including use of GCs;
- Veterinary medicine;
- Calibration of applicant's instruments; and
- Field studies.

If you wish to request authorization for the possession and use of self-shielded irradiators exceeding 37 terabecquerels (1,000 curies), submit DPH Form 45016, '*Application for Radioactive Material License Authorizing the use of Self Shielded Irradiators*'. WISREG-1556, Vol. 5, '*Guidance for Self-Shielded Irradiators*,' provides guidance for licensing of self-shielded irradiators.

This WISREG identifies the information needed to complete DPH form 45016, '*Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope*' (**Appendix A**),

Appendixes C through T contain additional information on various radiation safety topics.

Chapter HFS 157 ‘Radiation Protection’ requires the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the rule. Each applicant should read the rule and procedures provided carefully and then decide if the procedure addresses specific radiation protection program needs at the applicant’s facility. Applicants may adopt a provided procedure or they may develop their own procedures to comply with the rule.

In this guide, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in **Chapter HFS 157 ‘Radiation Protection’, Subchapter I ‘General Provisions’**. Rem and sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because **Chapter HFS 157 ‘Radiation Protection’, Subchapter III ‘Standards for Protection from Radiation’**, sets dose limits in terms of rem, not rad or roentgen. Furthermore, radioactive materials commonly used in Academic, Research & Development, and Other Licenses of Limited Scope emit beta and photon radiation, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem.

The format within this guide for each item of technical information is as follows:

- **Rule** - references the requirements from **Chapter HFS 157 ‘Radiation Protection’**, applicable to the item;
- **Criteria** - outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** - provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** - indicates that a written response is required and/or offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of Wisconsin according to DHFS’s guidelines. Submission of incomplete or inadequate information will

result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule and these instructions prior to submitting the application.

WHO REGULATES FACILITIES IN WISCONSIN

In the special situation of work at federally controlled sites in Wisconsin, it is necessary to know the jurisdictional status of the land to determine whether the Nuclear Regulatory Commission (NRC) or DHFS has regulatory authority. The NRC has regulatory authority over land determined to be under “exclusive federal jurisdiction,” while the DHFS has jurisdiction over non-exclusive federal jurisdiction land (see **Table 1**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. DHFS recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with DHFS or NRC regulatory requirements, as appropriate. The following table lists examples of regulation authority.

Table 1: Who Regulates the Activity

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [<i>10 CFR 30.12</i>])	NRC
Non-federal entity in non-agreement State, U.S. territory, or possession	NRC
Non-federal entity in WI at non-federally controlled site	DHFS
Non-federal entity in WI at federally-controlled site not subject to exclusive Federal jurisdiction	DHFS
Non-federal entity in WI at federally-controlled site subject to exclusive federal jurisdiction	NRC

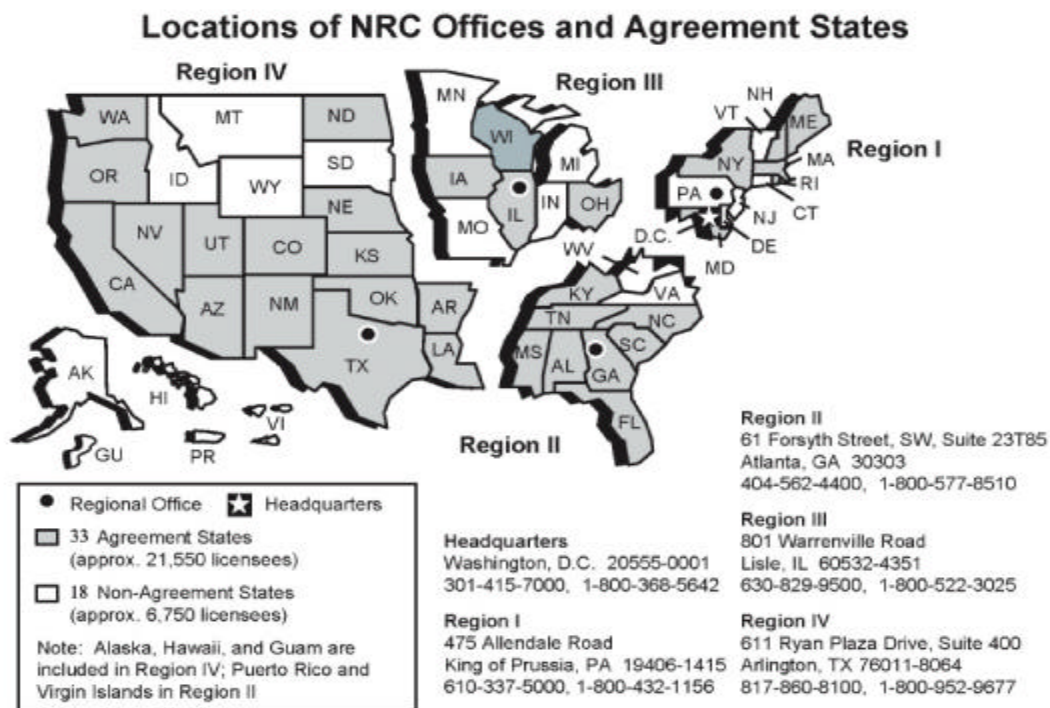


Figure 1: U.S. Map Location of NRC Offices and Agreement States

Reference: A current list of Agreement States (States that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their borders), (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices. NRC Office of State and Tribal Programs (STP) also provides the current list of Agreement States at web site: <http://www.hsrdo.nrl.gov/nrc/home.html>.

MANAGEMENT RESPONSIBILITY

"Management" refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have authority to provide necessary resources to achieve regulatory compliance. DHFS recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. DHFS believes that consistent compliance with its rules provides reasonable assurance that licensed activities will be conducted safely. DHFS also believes that effective management will result in increased safety and compliance. DHFS frequently finds ineffective management is the underlying cause of safety and compliance problems.

To ensure adequate management involvement, a management representative must be a person duly authorized to act for and on behalf of the applicant or licensee, and must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with **Chapter HFS 157 'Radiation Protection'**;
- Knowledge about the contents of the license and application;
- Compliance with current DHFS and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained;
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program;
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in **HFS 157.03** and **HFS 157.05(2)**, respectively;
- Obtaining DHFS's prior written consent before transferring control of the license; and
- Notifying DHFS in writing, within 10 days following filing of petition for voluntary or involuntary bankruptcy.

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read and follow **Chapter HFS 157 'Radiation Protection'**.

The following subchapters of **Chapter HFS 157 'Radiation Protection'** contain requirements applicable to this WISREG:

- Subchapter I 'General Provisions'
- Subchapter II 'Licensing of Radioactive Materials'
- Subchapter III 'Standards for Protection from Radiation'
- Subchapter X 'Notices, Instructions and Reports to Workers'
- Subchapter XI 'Inspection by the Department'
- Subchapter XII 'Enforcement'
- Subchapter XIII 'Transportation'

To request copies of the above documents call DHFS Radiation Protection Section at (608) 267-4797 or for electronic copy visit the following website:

http://www.dhfs.state.wi.us/dph_beh/RadioactiveMat/IndexRM.htm.

HOW TO FILE

Paper Application

Applicants for a materials license should do the following:

- Be sure to use the current guidance from DHFS in preparing an application;
- Complete DPH form 45016 '*Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope*' (**Appendix A**);
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers;
- Submit all documents, on 8-1/2 x 11 inch paper;
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit an original, signed application; and
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of certain responses as shown in this WISREG or submission of alternative procedures will require a more detailed review.

Personal employee information, i.e.; home address, home telephone number, Social Security Number, date of birth and radiation dose information should not be submitted unless specifically requested by DHFS.

WHERE TO FILE

Applicants wishing to possess or use radioactive material in Wisconsin are subject to the requirements of **Chapter HFS 157 ‘Radiation Protection’** and must file a license application with:

*Department of Health and Family Services
Radiation Protection Section
P.O. Box 2659
Madison, WI 53701-2659*

LICENSE FEES

The appropriate fee must accompany each application or license amendment request. Refer to **HFS 157.10** to determine the amount of the fee. DHFS will not issue the new license prior to fee receipt. Once the application review has begun, no fees will be refunded. Application fees will be charged regardless of DHFS's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to **HFS 157.10**.

Direct all questions about DHFS's fees or completion of **Item 12** of DPH form 45016, '*Application for Radioactive Material License for Academic, Research and Development and Other Licenses of Limited Scope*' (**Appendix A**) to DHFS Radiation Protection Section at (608) 267- 4797.

CONTENTS OF APPLICATION

Item 1: Type of Application

On the application check the appropriate box and list the license number for renewals and amendments.

Response from Applicant:

Item 1 Type Of Application (Check one box)

☐ New License ☐ Renewal License Number _____ ☐ Amendment License Number _____

Item 2: Name and Mailing Address of Applicant

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material. A division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent.

Response from Applicant :

Item 2 Name And Mailing Address Of Applicant:

Applicant's Telephone Number (Include area code):

Timely Notification of Change of Ownership or Control

Rule: *HFS 157.13(10) & (15)*

Criteria: Licensees must provide full information and obtain DHFS's written consent prior to transferring control of the license, or, as some licensees call it, "transferring the license".

Discussion: Changes in ownership may be the results of mergers, contractual agreements, buyouts, or majority stock transfers. Although it is not DHFS's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior DHFS written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid DHFS licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material; and
- Public health and safety are not compromised by the use of such materials.

Notification of Bankruptcy Proceedings

Rule: *HFS 157.13(10)*

Criteria: *HFS 157.13(10)(e)* states: "A licensee shall notify DHFS in writing within 10 days of filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify DHFS in writing, identifying the bankruptcy court in which the petition was filed and the date of filing."

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for compliance with all regulatory requirements. DHFS needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility).

Licensees must notify DHFS within 10 days of the filing of a bankruptcy petition.

This person is typically the proposed RSO, unless the applicant has named a different person as the contact. DHFS will contact this individual if there are questions about the application. Notify DHFS if the contact person or their telephone number has changed so that DHFS can contact the applicant or licensee in the future with questions, concerns or information. This notice is for "information only" and does not require a license amendment or a fee.

Item 3 Person To Contact Regarding Application:

Contact's Telephone Number (Include area code):

Discussion: Specify the street address, or other descriptive address (such as on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234), city and zip code for each permanent storage or use facility and field station. **A Post Office Box address is not acceptable** as illustrated in **Figure 2**, because DHFS needs a specific address to allow a DHFS inspector to find the use and/or storage location.

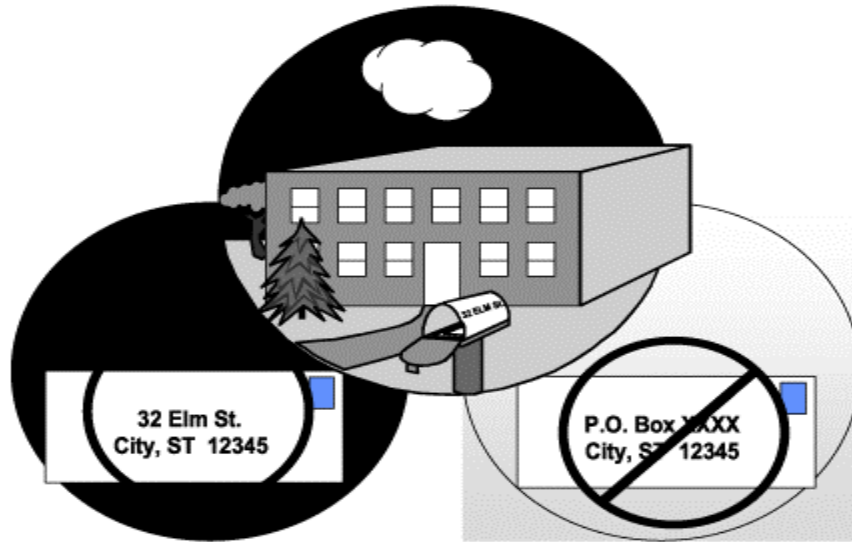


Figure 2: Location of Use

A DHFS-approved license amendment is required before receiving, using and storing licensed material at an address or location not included with the application or already listed on the license.

Granting a DHFS license does not relieve a licensee from complying with other applicable federal, state, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

As discussed later under ‘*Financial Assurance and Record Keeping for Decommissioning*,’ licensees must maintain permanent records describing where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of the specific locations or room numbers where licensed material is used or stored, and any records of spills or other unusual occurrences involving the spread of contamination in or around the licensee’s facilities.

Response from Applicant :

Item 4 Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use Post Office Box)	
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Is radioactive material used at locations for field studies or other off-site locations? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, please attach an additional sheet(s) with the locations address(es) and a list of activities to be conducted at each location.	

Item 5: Radiation Safety Officer (RSO)

Rule: *HFS 157.13(2)*

Criteria: RSOs must have training and specific experience, with the types and quantities of licensed material to be authorized on the license.

Discussion: The person responsible for implementing the radiation protection program is called the Radiation Safety Officer (RSO). The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are illustrated in **Figure 3** and described in **Appendix I**. DHFS requires the name of the RSO on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

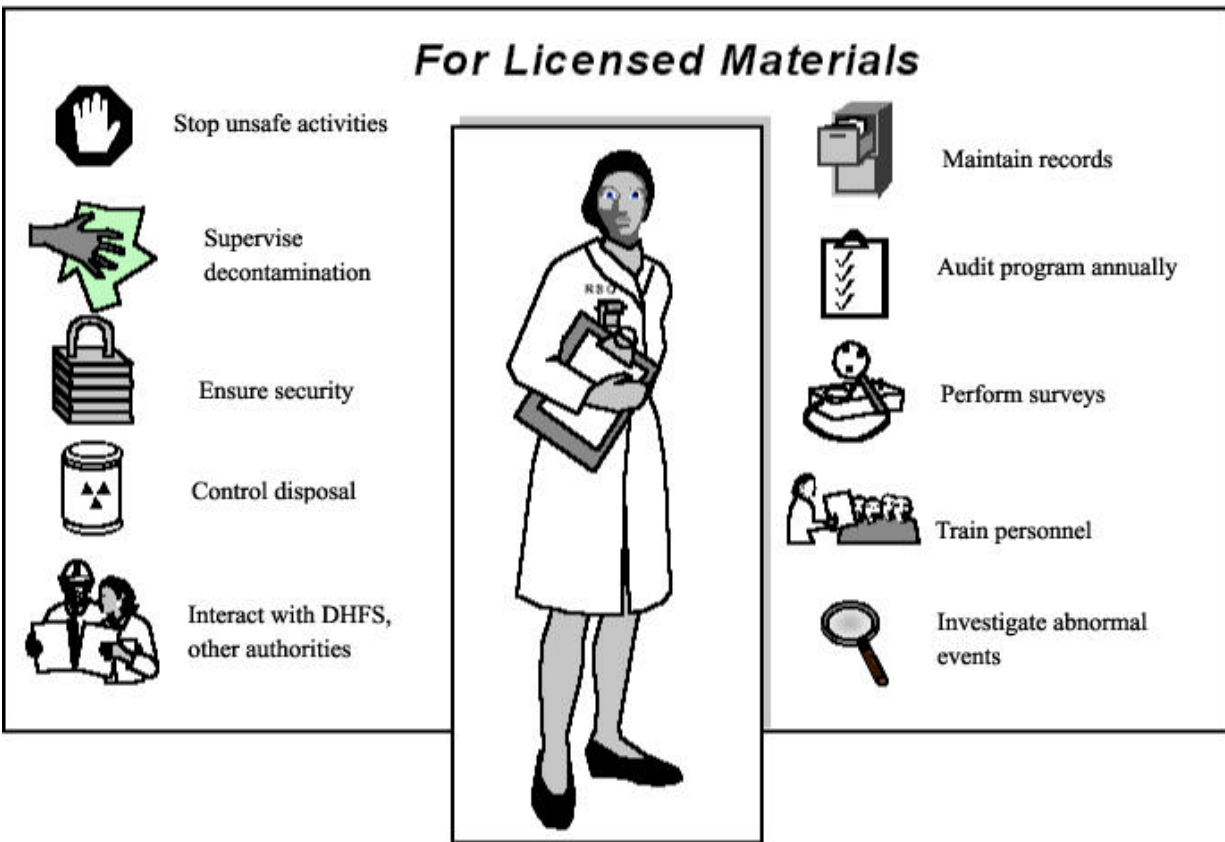


Figure 3:RSO Responsibilities. Typical duties and responsibilities of RSOs.

DHFS believes that to demonstrate adequate training and experience, the RSO should have: (1) as a minimum, a college degree at the bachelor level, or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of radioactive material to be used);
- **Chapter HFS 157, ‘Radiation Protection’**; and
- Hands-on use of radioactive materials.

The amount of training and experience needed will depend upon the type, form, quantity and proposed use of the licensed material requested. Ultimately, the proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. In addition, the RSO designee should have obtained the above training in a formal course designed for RSOs presented by an academic

institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts.

Response from Applicant :

Item 5 Radiation Safety Officer (RSO) (Check boxes)

- ☐ The name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

NAME _____

TELEPHONE NUMBER _____
(Include area code)

AND

- ☐ We will provide information demonstrating that the proposed RSO is qualified by training and experience.

Note: It is important to notify DHFS, as soon as possible, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to DHFS as part of an amendment request.

Item 6: Authorized Users (AU)

Rule: *HFS 157.13(2) HFS 157.21*

Criteria: Authorized users (AUs) must have adequate training and experience with the types and quantities of licensed material that they propose to use.

Discussion: An AU (also known as "principal investigator") is a person whose training and experience have been reviewed and approved by DHFS, who is named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements (See **Figure 4**). The AU is also responsible to ensure that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.



Figure 4: Authorized User. The Authorized User is responsible for the safe use of licensed material in his or her laboratory or area.

AUs must have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely, including maintaining security of, and access to, licensed material, and respond appropriately to events or accidents involving licensed material to prevent the spread of contamination.

DHFS believes that to demonstrate adequate training and experience the AU should have: (1) a college degree at the bachelor level, or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of radioactive material to be used); and
- Hands-on Use of Radioactive Materials.

The amount of training and experience needed will depend upon the type, form, quantity and proposed use of the licensed material requested, but it should cover the subjects stated.

An AU is considered to be supervising the use of radioactive materials when he/she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he/she is responsible for the safe use of radioactive material to assure that areas are not contaminated.

Applicants must name at least one individual who is qualified to use the requested licensed materials. In general, AUs must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

Response from Applicant :

Item 6 Authorized Users (Check both boxes)

☐ We will attach a list of each proposed authorized user with the types and quantities of licensed material to be used.

AND

☐ Information is attached demonstrating that each proposed authorized user is qualified by training and experience to use the requested licensed material.

Item 7: Training for Individuals Working in or Frequenting Restricted Areas

Rule: *HFS 157.03; HFS 157.05(2); HFS 157.13(2), (9) & (10); HFS 157.28(1); HFS 157.88*

Criteria: Individuals whose assigned duties involve exposure to radiation and/or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), must receive instruction commensurate with their duties and responsibilities, as required by *HFS 157.88(2)*.

Discussion: Before beginning work with licensed material, most individuals must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual must also receive periodic refresher training.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Particular attention should be given to persons performing work with radioactive materials that may require special procedures, such as hot cell work, waste processing, and animal handling. Also, ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and should emphasize practical subjects important to the safe use of licensed material. The guidance in **Appendix J** may be used to develop a training program. The program should consider both the topics pertinent for each group of workers and the method and frequency of training.

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program).

Response from Applicant :

Item 7 Training For Individuals Working In Or Frequenting Restricted Areas (Occupationally exposed individuals and ancillary personnel) (Check box)

☐ A description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors and the method and frequency of training is attached.

Item 8: Radioactive Material

Rule: *HFS 157.09(2); HFS 157.11(2); HFS 157.13(1) & (2)*

Criteria: An application for a license will be approved if the requirements of *HFS 157.13(2)* are met. In addition, licensees will be authorized to possess and use only those sealed sources and devices that are specifically approved or registered by the NRC or an Agreement State.

Discussion: Each authorized radioisotope is listed on the DHFS license by its element name, chemical and/or physical form, and the maximum possession limit. **Table 2** below shows the type of radioactive material covered by this guide.

Table 2: Types of Radioactive Material

Type of Material	Covered by this Guide	Examples
Radioactive Material	Yes	H-3, C-14, I-131, I-125, S-35, P-32, P-33, Ca-45, Ni-63, Cd-109, Cs-137
Source material	No	U, Th
Special nuclear material	No	Pu, etc.
Naturally occurring radioisotopes	No	Unsealed Ra-226
Accelerator-produced radioisotopes	Yes	Co-57, Na-22, Tl-201, Ga-67

The applicant should list each requested radioisotope by its element name and its mass number [e.g., carbon-14 (C-14)] in **Item 8**. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not required. For volatile radioactive material, however, it is necessary to specify whether the requested radioisotope will be acquired in free (volatile) or bound (non-volatile) form, because additional safety precautions are required when handling and using free form volatile material. For example, when requesting authorization to use tritium (H-3) or iodine-125 (I-125), the applicant must specify whether the material will be acquired in free form or bound form. If a radioisotope will be acquired in both free and bound forms, then separate possession limits for each form must be specified.

Applicants requesting an authorization to use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

If you plan to possess radioactive materials in excess of the quantities listed in **Chapter HFS 157 ‘Radiation Protection’ Appendix P**, then you must provide with the application either: (1) an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid, or (2) an emergency response plan for responding to the release in accordance with the criteria listed in **Chapter HFS 157 ‘Radiation Protection’ Appendix Q**.

The anticipated possession limit in MBq (millicuries) or GBq (curies) for each radioisotope should also be specified. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant’s needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half-life

greater than 120 days. These requirements are discussed in the section titled ‘Financial Assurance and Record Keeping for Decommissioning’.

Before proceeding further, applicants should determine if their proposed uses of licensed material are in excess of the quantities specified in **Chapter HFS 157 ‘Radiation Protection’, Appendix B**. It is not necessary to submit an application to DHFS for quantities of radioactive material that are covered by the exemption in **HFS 157.09(2)**, provided that they are received from entities that are licensed to distribute them. Similarly, certain prepackaged units (typically called kits) containing radioactive material for conducting “*in vitro*” clinical or laboratory tests, are distributed to persons who are generally licensed. Rules related to possession and use of such prepackaged kits under a general license are stated in **HFS 157.11(2)(f)**. Persons eligible for this general license are limited to physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, and hospitals; however, these persons are required to register with DHFS before acquiring or using these units, unless they have a DHFS license under **Chapter HFS 157 ‘Radiation Protection’, Subchapter VI ‘Medical Use of Radioactive Material’**.

Certain devices containing sealed sources of radioactive material, such as Electron Capture Devices in Gas Chromatographs (GCs), are authorized by DHFS, the NRC or another Agreement State for distribution to persons who are generally licensed as well as to persons who are specifically licensed. Generally licensed devices can be acquired by the users without obtaining a specific license from DHFS. Regulatory requirements for such devices possessed under a general license are stated in **HFS 157.11(2)**. Distributors of such devices must provide users with appropriate information related to the acquisition, use, and transfer of these generally licensed devices. Alternatively, GCs may be authorized on an ARDL specific license. **Appendix D** information shall be submitted in support of such a request.

A safety evaluation of sealed sources and devices is performed by the NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Information on SSD registration certificates may be obtained by contacting DHFS, the Registration Assistant by calling NRC’s toll-free number (800) 368-5642, extension 415-7231 or by visiting the following website: <http://www.hsrdr.gov/nrc/sources/index.cfm>. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to use those sources and devices specifically listed on their licenses. Applicants must provide the manufacturer’s name and model number for each requested sealed source and device so that DHFS can verify that they have been evaluated in an SSD Registration Certificate or specifically approved on a

license. See NRC NUREG – 1556, Vol. 3 *‘Applications for Sealed Source and Device Evaluation and Registration’*.

Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the sealed source and device designations registered with the NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining DHFS’s prior permission in a license amendment. To ensure that applicants use sources and devices according to the registration certificates, they should obtain a copy of the certificate and review it or discuss it with the manufacturer.

Response from Applicant :

Item 8 Radioactive Material (Attach additional pages if necessary)				
UNSEALED SOURCES				
Radioisotope				
Chemical/Physical Form				
Maximum Possession Limit				
Proposed Use				

SEALED SOURCES				
Radioisotope				
Chemical/Physical Form	SEALED SOURCE	SEALED SOURCE	SEALED SOURCE	SEALED SOURCE
Sealed Source Manufacturer or Distributor and Model Number				
Device Manufacturer or Distributor and Model Number				
Sealed Source Device Registration Sheet Number				
Maximum Possession Limit				
Proposed Use				

Purpose(s) for Which Licensed Material Will Be Used

Rule: *HFS 157.03; HFS 157.13(2)*

Criteria: The applicant must specify the purpose of use for each sealed and/or unsealed radionuclide requested. All sealed sources and devices containing licensed material shall be used only for the purpose for which they are designed, and according to manufacturer's (distributor's) instructions and recommendations for use as specified in the SSD Registration Certificate.

Discussion: Applicants should clearly specify the purpose for which each radioisotope will be used. The description should be detailed enough to allow DHFS to determine the potential for exposure to radiation and radioactive materials, to those working with radioactive materials and members of the public.

Research and development, as defined in *HFS 157.03*, does not include research involving the use of licensed material in or on humans. Applicants intending to use licensed materials for medical research involving humans must be authorized to do so pursuant to a license issued under **Chapter HFS 157 'Radiation Protection', Subchapter VI 'Medical Use of Radioactive Material'**, and should refer to WISREG-1556 Vol. 9, '*Guidance for Medical Use of Radioactive Materials*'.

Applicants may use the format given in **Table 3** to provide the requested information.

Table 3: Sample Format for Providing Information About Requested Radioisotopes

Radioisotope	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
H-3	Unbound/volatile	100 millicuries	Labeling of compounds
H-3	Bound/non-volatile	100 millicuries	In vitro studies; studies in small lab animals
P-32	Any	30 millicuries	In vitro studies; labeling of compounds
I-125	Unbound/volatile	30 millicuries	Protein iodination
I-125	Bound/non-volatile	50 millicuries	In vitro studies; studies in small lab animals; calibration of instruments
Cs-137	Sealed source, Mfg. name/ model number	20 millicuries	Calibration of instruments

Applicants should clearly specify if the licensed material will be used in animal studies and/or tracer studies. Use of licensed material in animals may be in research studies, or by veterinarians for diagnostic and therapeutic purposes. Applicants should also state whether the studies will be limited to small animals (e.g., rats, mice) or may also include larger animals (e.g., pigs, dogs, horses). Similarly, the veterinary use should specify whether the material will be used in pets (cats, dogs) or in farm animals

(cattle, horses, pigs). **Appendix H** provides guidance for developing radiation safety procedures for these studies and procedures.

Applicants should note that authorization from DHFS to use licensed material in animal and/or tracer studies does not relieve them of their responsibilities to comply with any other applicable Federal, state or local regulatory requirements.

Financial Assurance and Record Keeping for Decommissioning

Rule: *HFS 157.13(9) & (10); HFS 157.15*

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in *HFS 157.15* must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (F/A) for decommissioning. All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Licensees must transfer these records either to the new licensee before licensed activities are transferred or assigned in accordance with *HFS 157.13(10)(b)* or to DHFS before the license is terminated.

Discussion: DHFS wants to ensure that decommissioning will be carried out with minimum impact on the public, occupational health and safety, and the environment. There are two parts to this rule: financial assurance that applies to some licensees, and record keeping that applies to all licensees.

DHFS requirements for F/A and/or a DFP are designed to provide reasonable assurance that the technical and environmental components of decommissioning are carried out and unrestricted use of the facilities is possible at the conclusion and/or termination of licensed activities. DHFS wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and on the environment. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available (see **Figure 5**). Applicants are required to submit an F/A and/or a DFP when the possession of radioactive material of half-life ($T_{1/2}$) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a DFP and/or an F/A (or neither) are stated in *HFS 157.15*.

Table 4 is a partial list of radioisotopes of $T_{1/2} > 120$ days with their corresponding limits in excess of which an F/A or a DFP is required; however, it is DHFS's experience that most ARDL licensees use only

a few of these radioisotopes and that the most frequently used radioisotopes are hydrogen-3 (H-3), C-14, chlorine-36 (Cl-36), and calcium-45 (Ca-45) in unsealed form. The amounts of such radioisotopes required by ARDL licensees rarely exceed the limits that require submitting a DFP or an F/A. See **Table 4** for possession limits and guidance for submitting either a DFP or an F/A. Radioisotopes of $T_{1/2} > 120$ days are listed in column 1. Column 2 lists the corresponding possession limits of radioisotopes in unsealed form requiring an F/A. Column 3 lists the corresponding possession limits of radioisotopes in unsealed form requiring the submittal of a DFP. These limits apply when only one of these radioisotopes is possessed.

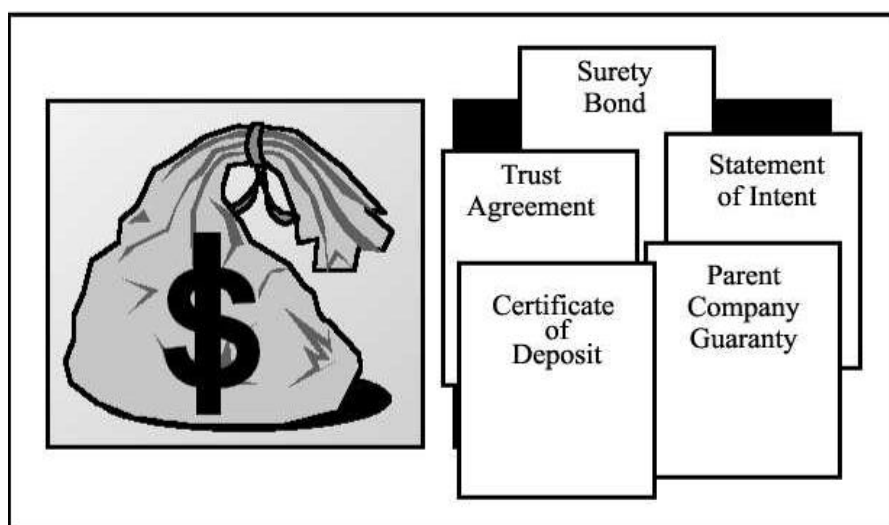


Figure 5: Methods of Certification of Financial Assurance for Decommissioning

Applicants can use the data from **Table 4** below or the method given in **Appendix G** to determine if an F/A is required and the amount that is required when more than one of these radioisotopes is requested. Most of the ARDL licensees use a small number of these radioisotopes, and in many cases the use is limited to only H-3 and C-14. Such licensees may be able to adjust the amounts of these radioisotopes so that the financial assurance requirement is not applicable.

Table 4: Commonly Used Unsealed Licensed Material Requiring Financial Assurance & Decommissioning Funding Plan

Column 1: Radioisotope	Column 2: Limit for F/A (millicuries*)	Column 3: Limit for DFP (millicuries*)
Calcium-45	10	1,000
Carbon-14	100	10,000
Chlorine-36	10	1,000
Hydrogen-3	1,000	100,000
Zinc-65	10	1,000

* 1 millicurie = 37 MBq

NRC Regulatory Guide (RG) 3.66, ‘*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*’, contains approved wording for each mechanism authorized by the rule to guarantee or secure funds except for the Statement of Intent for government licensees.

Record Keeping

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in **HFS 157.15(7)**. All licensees are required to maintain these records in an identified location until the site is released for unrestricted use (see **Figure 6**). In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee prior to transfer of the licensed activities. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records shall be transferred to DHFS.

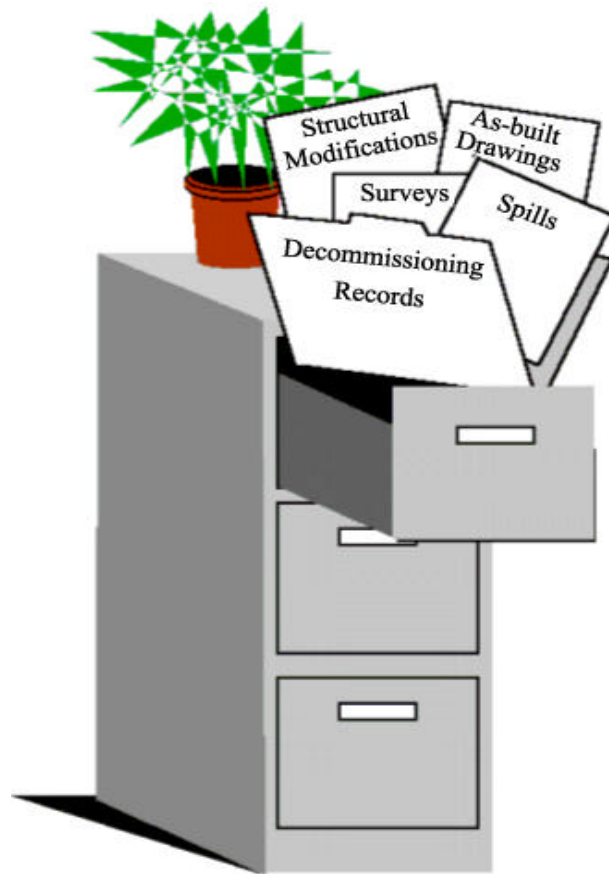


Figure 6: Types of Records That Must Be Maintained for Decommissioning

HFS 157.15(7) Requirements for Disposition of Records Important to Decommissioning:

- Before licensed activities are transferred or assigned according to ***HFS 157.15(10)(b)***, transfer to the new licensee
- OR**
- Before the license is terminated, transfer records to DHFS.

References: Can be accessed on the NRC website at www.nrc.gov.

- NRC Regulatory Guide 3.66, '*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72.*'
- NRC Policy and Guidance Directive FC 90-2 (Revision. 1), '*Standard Review Plan for Evaluating Compliance with Decommissioning Requirements.*'

Item 9: Facilities and Equipment

Rule: *HFS 157.13(2); HFS 157.15; HFS 157.21*

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

Discussion: Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the uses of the types and quantities of radioactive materials to be used.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed, in case changes are required as a result of the application review. This also ensures the adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant may not possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.

Applicants are reminded that records important to decommissioning include the following:

- As-built drawings and modifications of structures and equipment in restricted areas;
- As-built drawings and modifications of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination; and

- Records of spills and unusual occurrences that may result in contamination of the facility or site.

These records are required to be maintained in an identifiable location. Facilities are required to meet DHFS criteria prior to release. Therefore, careful facility design is important to prevent contamination, or facilitate decontamination, reducing the costs needed for decommissioning. For further information, see the section titled, ‘Financial Assurance and Record Keeping for Decommissioning.’

For additional guidance regarding facilities and equipment, refer to **Appendix K**.

If radioactive materials will be used with animals, include a description of the animal handling and housing facilities. (See **Appendix H**)

Response from Applicant :

Item 9 Facilities And Equipment (Check all that apply)

- ☐ A description is provided of the facilities and equipment at each location where radioactive material will be used. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. (Diagrams are attached)

NOTE: See Appendix K of WISREG ‘Guidance for Academic, Research and Development and Other Licenses of Limited Scope’.

AND/OR

- ☐ For animal use, a description is provided of the facilities and equipment at each location where radioactive material will be used. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. (Diagrams are attached)

NOTE: See Appendices K and H of WISREG ‘Guidance For Academic, Research and Development and Other Licenses Of Limited Scope’.

AND IF APPLICABLE

- ☐ A description showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety is provided.

AND/OR

- ☐ For radioactive materials that may become airborne, diagrams contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. (Diagrams are attached)

Item 10: Radiation Safety Program

Item 10.1: Audit Program

Rule: *HFS 157.21; HFS 157.31(2)*

Criteria: Licensees must review the content and implementation of their radiation protection programs at least annually to ensure the following:

- Compliance with DHFS and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (*HFS 157.21*); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: **Appendix L** contains a sample audit program that is specific to ARDL licensees and is acceptable to DHFS. All areas indicated in **Appendix L** may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit. Generally, audits are conducted at least once every 12 months.

Currently, the DHFS's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of radioactive material users to determine if, for example, Safe Use and Emergency Procedures are available and are being followed.

If an audit identifies violations of DHFS requirements, the licensee should first evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. NRC Information Notice (IN) 96-28, '*Suggested Guidance Relating to Development and Implementation of Corrective Action*' dated May 1, 1996, provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to DHFS. Licensees are encouraged to contact DHFS for guidance if there is any uncertainty regarding a reporting requirement. DHFS routinely reviews licensee's records to verify if appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. DHFS can exercise discretion and may

elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

Licensees must maintain records of these audits and other reviews of program content and implementation for 3 years from the date of the record. Records of these audits should include the following information: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records must be maintained for inspections by DHFS.

Response from Applicant :

Item 10.1 Audit Program

The applicant is not required to submit its audit program to DHFS for review during the licensing phase. This matter will be examined during an inspection.

References:

NRC Information Notice 96-28, '*Suggested Guidance Relating to Development and Implementation of Corrective Action*' dated May 1, 1996. Information Notice 96-28 is available on the Internet at <http://www.nrc.gov>.

Item 10.2: Radiation Monitoring Instruments

Rule: *HFS 157.13(2); HFS 157.25(1); HFS 157.31(3)*

Criteria: Licensees must possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Licensees shall possess, or have access to, calibrated radiation detection/measurement instruments or licensed services to perform, as necessary the following:

- Package surveys;
- Contamination surveys;
- Sealed source leak tests;
- Air sampling measurements;

- Bioassay measurements;
- Effluent release measurements; and
- Unrestricted area dose rate measurements.

For the purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the survey instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters;
- Portable or stationary dose rate or exposure rate meters;
- Single or Multichannel Analyzers;
- Liquid Scintillation Counters (LSC);
- Gamma Counters;
- Proportional Counters; and
- Solid State Detectors.

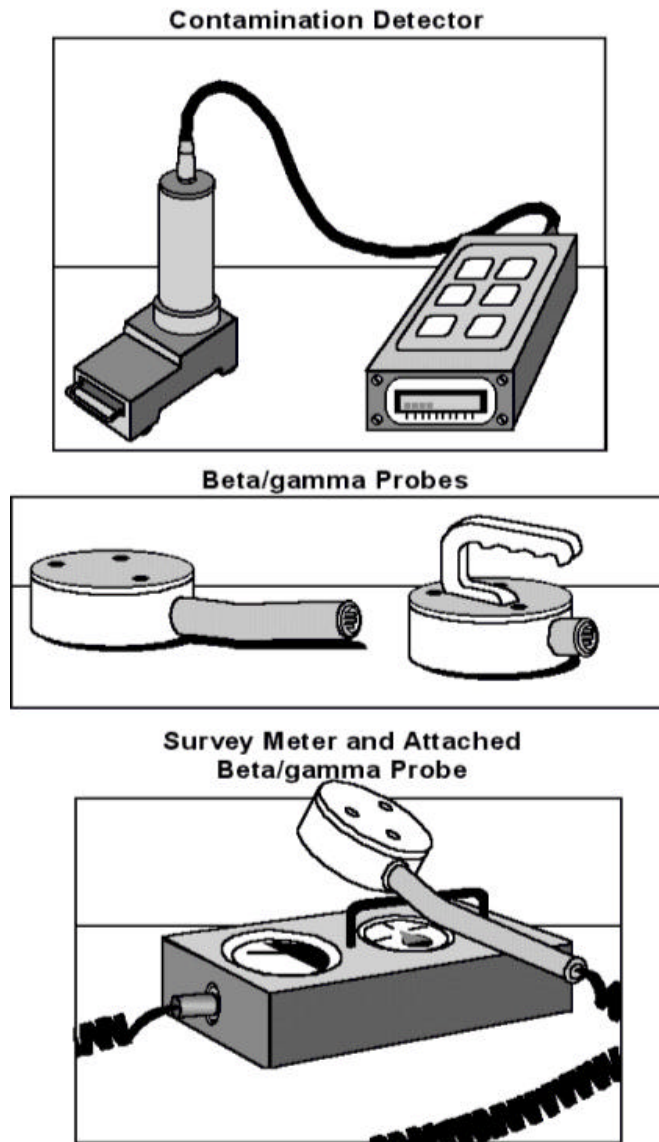


Figure 7: Examples of Portable Instruments Used in Laboratory Setting.

The choice of instrument should be appropriate for the type of radiation to be measured, and for the type of measurement to be taken (count rate, dose rate, etc.). **Figure 7** illustrates some common survey instruments used for contamination surveys. Applications should include descriptions of the instrumentation available for use and instrumentation applicants intend to purchase prior to starting licensed activities. The description should include type of instrument and probe, and the instrument's intended purpose.

DHFS requires that calibrations be performed by the instrument manufacturer or a person specifically authorized by DHFS, the NRC or another Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations shall submit

procedures for review. **Appendix M** provides information about instrument specifications and calibration procedures.

Response from Applicant :

Item 10.2 Radiation Monitoring Instruments (Check one box)

☐ We will use instruments that meet the radiation monitoring instruments specifications published in Appendix M of WISREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. We reserve the right to upgrade our survey instruments as necessary.

OR

☐ We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M of WISREG 'Guidance for Academic, Research and Development and Other License of Limited Scope'. Additionally we will implement the survey meter calibration program published in Appendix M of WISREG 'Guidance for Academic Research and Development and Other License of Limited Scope'. We reserve the right to upgrade our survey instruments as necessary.

OR

☐ We will provide a description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. We reserve the right to upgrade our survey instruments as necessary. (Procedures are attached)

Item 10.3: Material Receipt and Accountability

Rule: *HFS 157.06(1); HFS 157.11(2); HFS 157.13(10), (15) & (18); HFS 157.15; HFS 157.28(1); HFS 157.29(6); HFS 157.30(1); HFS 157.32(1)*

Criteria: Licensees must do the following:

- Develop, implement, and maintain written procedures for safely opening packages;
- Develop, implement, and maintain procedures to ensure security and accountability of licensed material; and
- Maintain records of receipt, transfer, and disposal of licensed material.

Discussion: Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with *HFS 157.29(6)*. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

Licensees need to make arrangements to receive radioactive packages when they are delivered or to be notified when radioactive packages arrive at the carrier's terminal so that the licensee can pick up the package expeditiously.

A sample procedure for safely opening packages containing licensed materials is included in **Appendix N**.

In limited scope radiation safety programs, the RSO or his/her staff usually receives the incoming package directly from the carrier, and performs all verification, surveying, opening, and documentation for inventory. The package is then delivered to the AU, or the AU retrieves the package from the RSO. If the package is transported over public roads by the licensee, it must be repackaged and transported in accordance with DOT regulations.

If the package of licensed material is delivered to the licensed facility's receiving department (Receiving), individuals working in that department should be trained to do the following:

- Identify the package as radioactive by labeling and shipping papers;
- Segregate the package from other incoming items in a secured area until released by the RSO;
- Notify the RSO.

When notified that a package of licensed material has arrived, the RSO or his/her staff should retrieve the package and follow the safe opening procedures.

HFS 157.29(6) states the requirements for monitoring packages containing licensed material. These requirements are described in **Table 5 below**.

Table 5: Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A	Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Greater Than Type A	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than Type A	None	None
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Less Than Type A	Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Not Labeled	Licensed Material	None	None
Damaged	Licensed Material	Contamination Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package

* Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has three hours after the beginning of the next work day to perform the required surveys.

HFS 157.29(6) requires that the licensee immediately notify the final delivery carrier and, by telephone, and either telegram or facsimile, DHFS, when removable radioactive surface contamination or external radiation levels exceeds the limits of **49 CFR 173.443**.

As illustrated in **Figure 8**, licensed materials must be tracked from "receipt to disposal" in order to ensure accountability and to ensure that possession limits listed on the license are not exceeded.

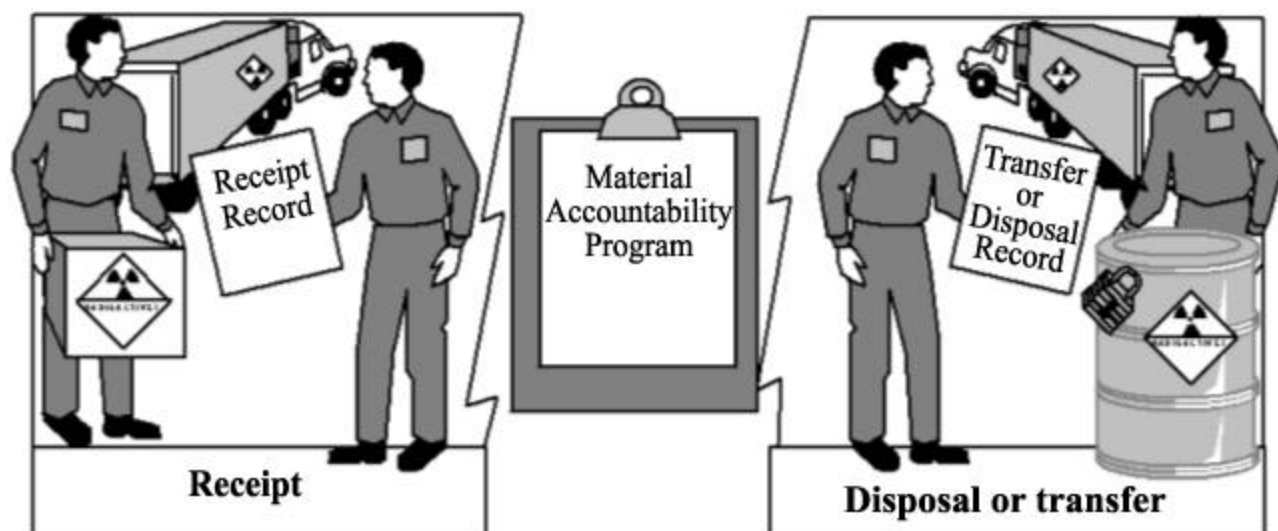


Figure 8: Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal of licensed material.

Licensees frequently possess radioactive material, which is generally licensed or distributed to them as an exempt quantity in addition to that which is specifically listed on their license. *HFS 157.11* provides information regarding generally licensed devices. Any person who acquires, receives, possesses, uses, or transfers a generally licensed device must do so in accordance with the provisions of the general license. Generally licensed material possessed by a specific licensee may continue to be possessed under a general license. A specific license does not automatically remove general licensee status nor automatically "move" generally licensed material to the specific license. DHFS recognizes that multiple authorizations can create some confusion and, therefore, a specific licensee always has the option of receiving and possessing radioactive materials that "qualify" for a general license, by adding these to its specific license.

Similarly, radioactive material received by a specific licensee, that is distributed to them under an exemption from the requirements for a license, is not subject to the terms and conditions of the specific license. Any person may receive radioactive material that is exempt from the requirements of a license pursuant to *HFS 157.04* and *HFS 157.09*. Such materials may include "exempt quantities" of radioactive materials that do not exceed the applicable quantity listed in **Chapter HFS 157 'Radiation Protection' Appendix B**, as well as items such as smoke detectors and self-luminous watches, that are distributed in accordance with other DHFS requirements. Most licensees do not possess or control these type of devices under the provisions of their specific license and DHFS does not require or encourage this practice; however, as stated above, the specific licensee always has the option of adding these materials to its license, and controlling them under the conditions of the specific license. In any case, licensees are required to ensure that dose limits are not exceeded, whether or not the dose results from licensed sources or unlicensed sources.

Some facilities may have separate laboratories or locations which use material for in-vitro assay that may be possessed under the general license in *HFS 157.11(2)(f)*. Each location is a separate general license from the other. The multiple locations are not considered to operate under a single general license and are not considered part of the specific license. The possession limit of 7.4 MBq (200 microcuries), only applies to a total amount of I-125, iodine-131 (I-131), selenium-75 (Se-75), iron-59 (Fe-59) or cobalt-57 (Co-57) used or stored in one location.

It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees must have in place an accountability and control system for promptly detecting losses of licensed material.

Licensees who use and/or possess sealed sources are required by license condition to perform inventories of sealed sources every six months. Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should confirm that these sealed sources have not been disturbed at least every 6 months. Licensees are also required to conduct leak tests of sealed sources at 6-month intervals (or at longer intervals as specified in the SSD Registration Certificate). Since the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program.

With regard to unsealed licensed material, licensees use various methods (e.g., computer programs, manual ledgers, and logbooks) to account for receipt, use, transfer, disposal, and radioactive decay. These methods help to ensure that possession limits are not exceeded.

To ensure that only trained, experienced, and authorized individuals use or supervise the use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be established for the procurement of licensed materials that may be obtained outside the normal channels, e.g., through the loan or other transfer of materials without purchase or through surplus. A sample procedure for ordering and receiving radioactive material is included in **Appendix N**.

DHFS requirements applicable to transfers are stated in *HFS 157.13(15)*. Sample policy transfer statements are included in **Appendix N**. Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components including refrigerators and freezers will become contaminated. Removal of these items for maintenance, repair, or disposal should also be carefully controlled.

Licensees must maintain records of receipt, transfer, and disposal (as waste) of all licensed material. **Table 6** below lists each type of record and how long the record must be maintained. Other records such as transfer records could be linked to radioactive material inventory records. Receipt records should also document cases where excessive radiation levels or radioactive contamination were found on packages or containers of material received and describe the action taken.

Table 6: Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until DHFS terminates the license
Important to decommissioning	Until the site is released

Receipt, transfer, and disposal records typically contain the following information:

- Radionuclide and activity (in units of becquerels or curies), and date of measurement of radioactive material;
- For each sealed source, manufacturer, model number, location, and, if needed for identification, serial number and as appropriate, manufacturer and model number of device containing the sealed source;
- Date of the transfer and name and license number of the recipient, and description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number); and
- For licensed materials disposed of as waste, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.).

See **Item 12 ‘Waste Management’** for additional information.

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by **HFS 157.15**. See the section on ‘Financial Assurance and Record Keeping for Decommissioning’ for additional information.

Response from Applicant :

Item 10.3 Material Receipt And Accountability (Check all that apply)

UNSEALED SOURCES

- ☐ We will submit procedure(s) for ensuring radioactive material accountability.

SEALED SOURCES

- ☐ We will perform physical inventories at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.

OR

- ☐ We will submit a description of the frequency and procedures for ensuring that no sealed sources have been lost, stolen or misplaced. (Description is attached)

Note:

No response is needed from applicants for package opening procedures. Package opening procedures will be reviewed during DHFS inspections.

Alternative responses will be evaluated using the Criteria listed above.

Item 10.4: Occupational Dose

Rule: *HFS 157.22(1-4), (7) & (8); HFS 157.25(1) & (2); HFS 157.27(3); HFS 157.31(6); HFS 157.32(5); Chapter HFS 157'Radiation Protection', Appendix E*

Criteria: The use of individual monitoring devices for external dose is required for:

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 5 mSv (0.5 rem) deep-dose equivalent.
 - 15 mSv (1.5 rems) eye dose equivalent.
 - 50 mSv (5 rems) shallow-dose equivalent to the skin.
 - 50 mSv (5 rems) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 0.5 mSv (0.05 rem) deep-dose equivalent.
 - 1.5 mSv (0.15 rem) eye dose equivalent.
 - 5 mSv (0.5 rem) shallow-dose equivalent to the skin.
 - 5 mSv (0.5 rem) shallow-dose equivalent to any extremity.
- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1 mSv (100 mrem) deep-dose equivalent, although the dose limit applies to the entire gestation period; and
- Individuals entering a high or very high radiation area.

Internal exposure monitoring (not necessarily individual monitoring devices) is required for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable ALIs for ingestion and inhalation.
- Minors likely to receive in 1 year a committed effective dose equivalent in excess of 1 mSv (100 mrem).

- Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv (100 mrem).

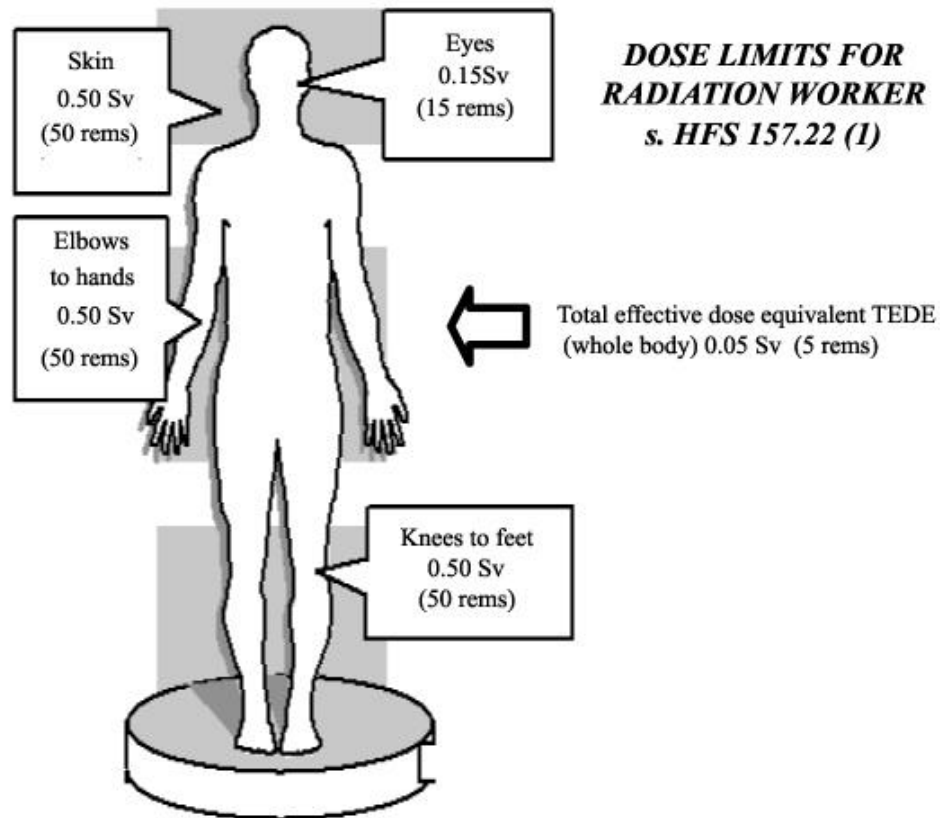


Figure 9: Annual Dose Limits for Occupationally Exposed Individuals.

Discussion: According to *HFS 157.25(2)*, if an adult (individual) is likely to receive in 1 year a dose greater than 10% of any applicable limit (See **Figure 9** for annual dose limits), monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in NRC Regulatory Guide 8.34, *Monitoring Criteria and Methods to Calculate Occupational Doses*, dated July 1992.

If this prospective evaluation shows that the individual's dose is not likely to exceed 10% of any applicable regulatory limit, there are no recordkeeping or reporting requirements. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this

prospective evaluation. When determining the need for monitoring, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered, including any recordkeeping and reporting requirements.

If an evaluation determined that monitoring was not required and a subsequent evaluation indicates that the 10% regulatory threshold may or will be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported (if required). These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

If the prospective dose evaluation shows that the individual is likely to exceed 10% of an applicable limit, monitoring is required per **HFS 157.25(2)**. Recordkeeping of the results of monitoring performed regardless of the actual dose received is required by **HFS 157.31(7)**.

A common method for dose evaluation is to monitor workers' dose with whole body and extremity dosimetry (TLDs film, ring badge, etc.) provided by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved dosimetry service. Workers are typically monitored for a year or more to determine actual annual dose. The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be reevaluated if there are changes to the licensee's program, such as procedures, frequency of use, quantity of licensed material used, isotopes used, etc.

For guidance about methodologies for determination of internal occupational dose and summation of occupational dose, refer to NRC Regulatory Guide 8.34, '*Monitoring Criteria and Methods to Calculate Occupational Doses*' dated July 1992, and NRC Regulatory Guide 8.9, '*Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*' dated July 1993. NRC also has additional Regulatory Guides that have been developed for specific isotopes such as H-3 and iodine. For copies of these guidance documents contact DHFS or access the NRC's web site at: <http://www.nrc.gov>.

Response from Applicant :

Item 10.4 Occupational Dose (Check one box)

☐ We will maintain, for inspection by DHFS, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in s. HFS 157.22.

OR

☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

Item 10.5: Public Dose

Rule: *HFS 157.03; HFS 157.23(1) & (2); HFS 157.28(1); HFS 157.31(8)*

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.

Discussion: "Public dose" is defined in *HFS 157.03* as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individuals assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

For guidance about accepted methodologies for determining dose to members of public, please refer to **Appendix O**.

Figure 10 shows the steps to calculate the annual dose to an individual member of the public.

**Calculating the Annual Dose to an
Individual Member of the Public**

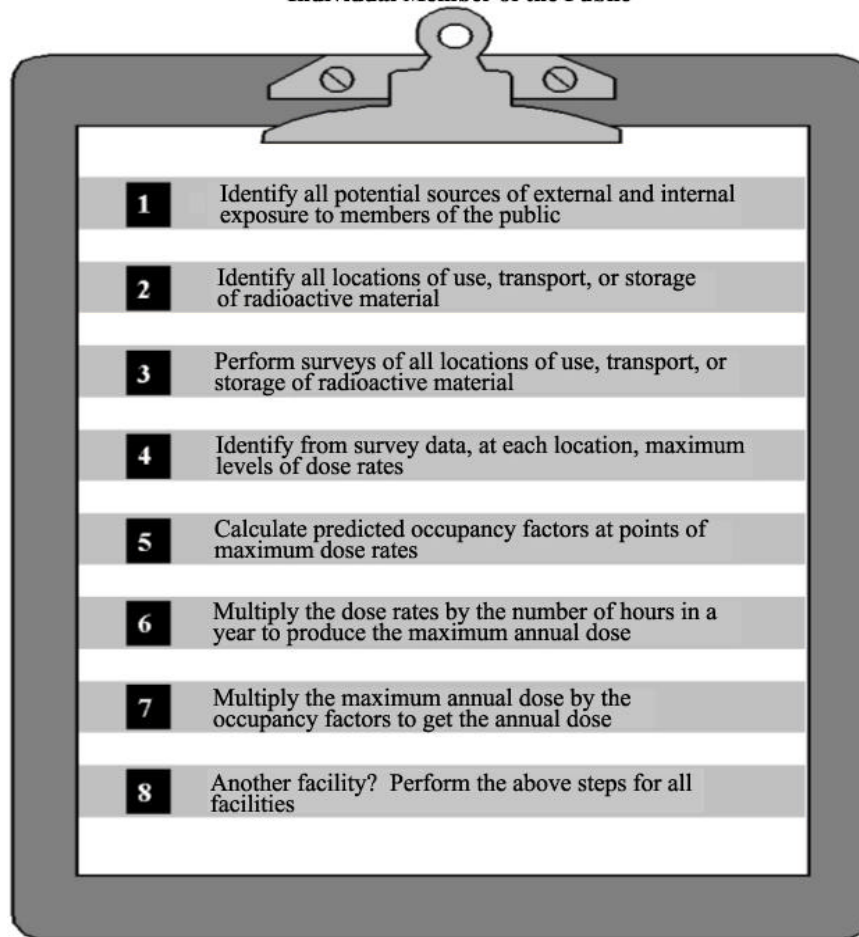


Figure 10: Calculating Public Dose. Steps to calculate the annual dose to an individual member of the public (see **Appendix O** for more information about occupancy factors).

There are many possible internal dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

- Airborne radioactive material
- Waterborne radioactive material
- External radioactive exposure.

The licensee should review these major pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with **HFS 157.23(2)**. The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to the section titled 'Surveys.'

HFS 157.31(8) requires that licensees maintain records sufficient to demonstrate compliance with the dose limits for members of the public until DHFS terminates the license. Refer to **Appendix O** for additional guidance regarding compliance with the recordkeeping requirements.

Response from Applicant :

Item 10.5 Public Dose

No response is required in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

Item 10.6: Safe Use of Radionuclides and Emergency Procedures

Rule: *HFS 157.13(1), (10) & (17); HFS 157.21; HFS 157.28(1); HFS 157.29(2-5); HFS 157.32(1-3); HFS 157.88(1); Chapter HFS 157 'Radiation Protection', Appendix P*

Criteria: Licensees are required to do all of the following:

- Keep radiation doses to workers and members of the public ALARA;
- Ensure security of licensed material; and
- Make the required notifications of events to DHFS.

Discussion: Licensees are responsible for the security and safe use of all licensed material from the time it arrives at their facility until it is used, transferred, and/or disposed. Licensees should develop and maintain written procedures to ensure safe use of licensed material, and the procedures should also include operational and administrative guidelines. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

General Safety Procedures

The written procedures should include the following elements:

- Contamination Controls;
- Waste Disposal Practices;
- Personnel and Area Monitoring (including limits);
- Use of Protective Clothing and Equipment;

- Record Keeping Requirements;
- Reporting Requirements; and
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Use of appropriate shielding (see **Figure 11**); and
- Frequent change of gloves to minimize exposure to the individual and to avoid spread of contamination in the laboratory.

Applicants should also develop radioisotope-specific procedures based on the respective hazards associated with the radioisotopes. General safety guidelines are described in **Appendix P**. Applicants should use these guidelines to develop procedures for the safe use of radioisotopes.

Licensees should determine if they have areas that require posting in accordance with *HFS 157.29(2)*, unless they meet the exemptions listed in *HFS 157.29(3)*. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with *HFS 157.29(4)*, unless they meet the exemptions in *HFS 157.29(5)*.

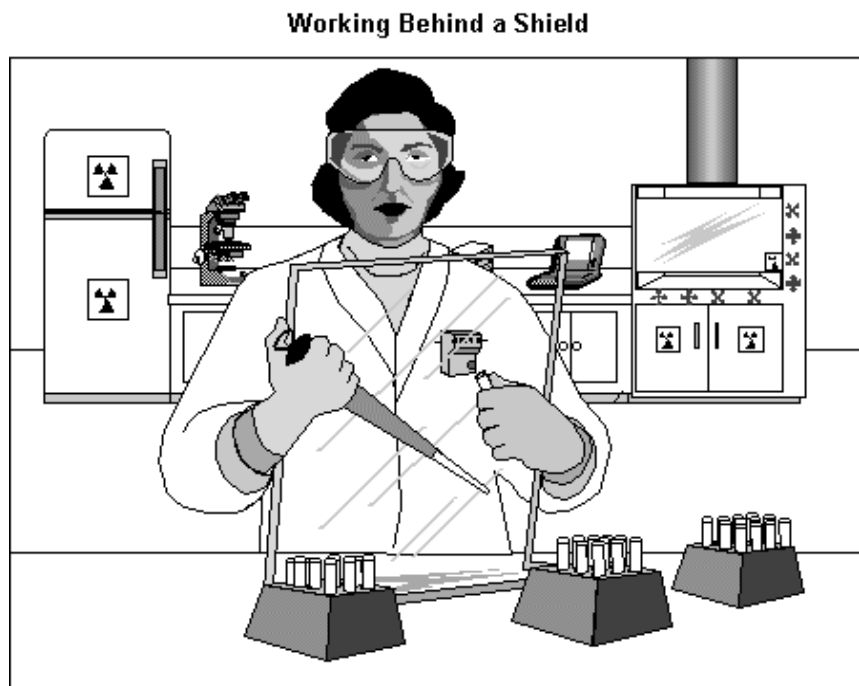


Figure 11: Use of Appropriate Shielding. This worker is using high density plastic shielding, which is appropriate for radioisotopes that emit beta radiation.

Security Procedures

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who are not knowledgeable about radioactive materials can not be exposed to or contaminated by the material, and can not take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material, or to prevent persons from removing the material from the area. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include: storage and use of licensed materials only in restricted areas; limiting access to an entire facility or building or portion of the building only to radiation workers; providing storage areas that can be locked to prevent access to the material; and implementing procedures that require a radiation worker to be with "line of sight" of the materials whenever licensed materials are in use. Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may be required to security procedures at facilities which may have unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment, and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, sabotage, fires, floods, etc., can adversely affect the safety of personnel and members of the public. It is therefore necessary to develop written procedures to minimize, as much as possible, the impact of these incidents on personnel, members of the public, and the environment. Applicants who plan to possess quantities of material in excess of the applicable amounts listed in **Chapter HFS 157 ‘Radiation Protection’ Appendix P** are also required to submit an ‘Emergency Response Plan for Responding to a Release’.

Applicants should establish written procedures to handle events ranging from a minor spill (see **Figure 12**) to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except

for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should have a clear understanding of their role in an emergency with step-by-step instructions and clear direction of whom to contact.

Licensees should have readily available a sufficient number of appropriate and calibrated survey instruments. Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished as necessary. **Appendix P** includes model emergency procedures. Applicants shall develop procedures incorporating the safety features included in these model procedures.

Collection of Bioassay Samples

In the event of an emergency where an individual became contaminated and radioactive material was taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required.

Frequently, this estimate is made by performing bioassay of the individual. Bioassays may be performed through direct methods such as whole body counting or thyroid counting, where the radioactive material in the body can be directly measured using appropriate instruments. Bioassays may also be performed through indirect means by sampling urine or other excreta from the body, and calculating the intake from the amount of material detected in the samples, the time between suspected intake and sample collection, and knowledge of the rate of excretion of the compound and/or radionuclide from the body. While there are many ways to perform the calculations, including using computer models, the method of calculation is only as good as the quality of the samples and analyses performed. Because a dose estimate may be required, bioassay procedures for a suspected intake may differ from those in a routine bioassay screening program, and your radiation safety program should include procedures and equipment for appropriate sample collection in an emergency. The following items should be considered in developing your procedures:

- Type of bioassay that must be performed (direct or indirect);
- Number of samples or data points to be collected;
- Frequency of sampling (hourly, daily, weekly, once?, etc.);
- Size of the sample to be collected (24-hour urine collection?);
- Ease/difficulty of sample collection; and
- Need for written instructions to be provided to the sample collector, who may be the contaminated individual.



Figure 12: Proper Handling of Incident. Panels 1 & 2 indicate how contamination can be spread if the incident is not handled properly as in panels 3 & 4.

Response from Applicant :

Item 10.6 Safe Use Of Radionuclides And Emergency Procedures (Check all that apply)

- ☐ We will develop, implement and maintain safe use of radionuclides and emergency procedures that will meet the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in WISREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. (Procedures are Attached)

AND/OR

- ☐ For Gas Chromatographs, we will submit the information requested in Appendix D of WISREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. (Information is attached)

AND/OR

- ☐ For use of radionuclides in animals, we will develop, implement and maintain safe use of radionuclides and emergency procedures that will meet the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in WISREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'. (Procedures are Attached)

Note: See Appendix H 'Considerations for Lab Animals and Veterinary Medical Use' of WISREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope' for additional information.

Item 10.7: Surveys

Rule: *HFS 157.06(3); HFS 157.24; HFS 157.25(1); HFS 157.31(3)*

Criteria: Licensees are required by *HFS 157.25(1)* to make surveys of potential radiological hazards in their workplace. DHFS requires testing to determine whether there is any radioactive leakage from sealed sources. Records of surveys and leak tests results must be maintained.

Discussion: Surveys are evaluations of radiological conditions and potential hazards (See **Figure 13**). These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

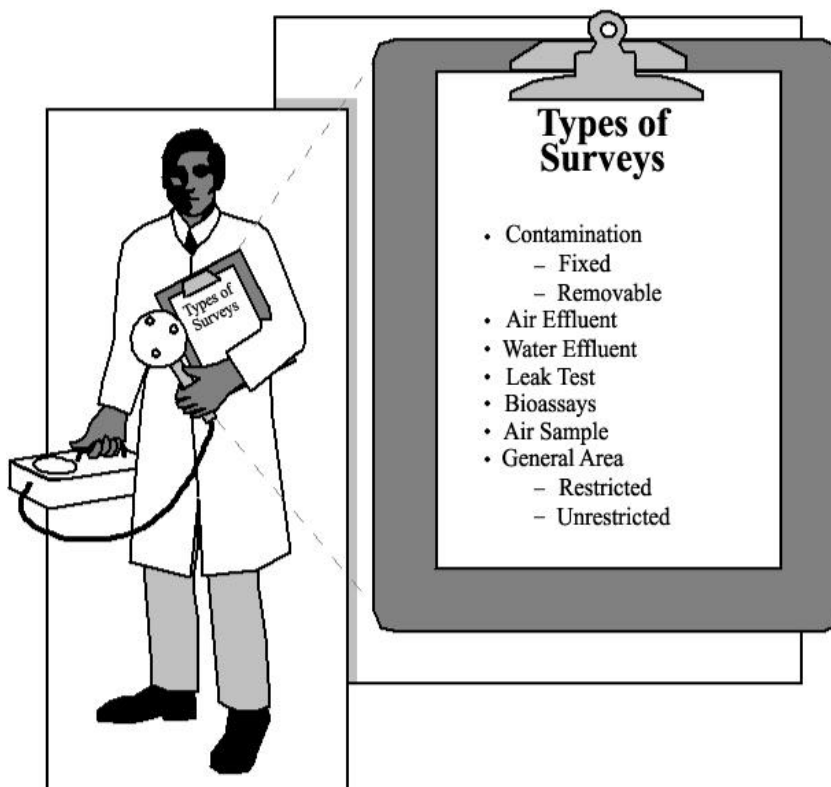


Figure 13: Types of Surveys. There are many different types of surveys performed by ARDL licensees.

Radiation surveys are used to detect and evaluate contamination of:

- Facilities;
- Equipment;
- Personnel (during use, transfer, or disposal of licensed material) (See **Figure 14**); and
- Restricted and Unrestricted Areas.

Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

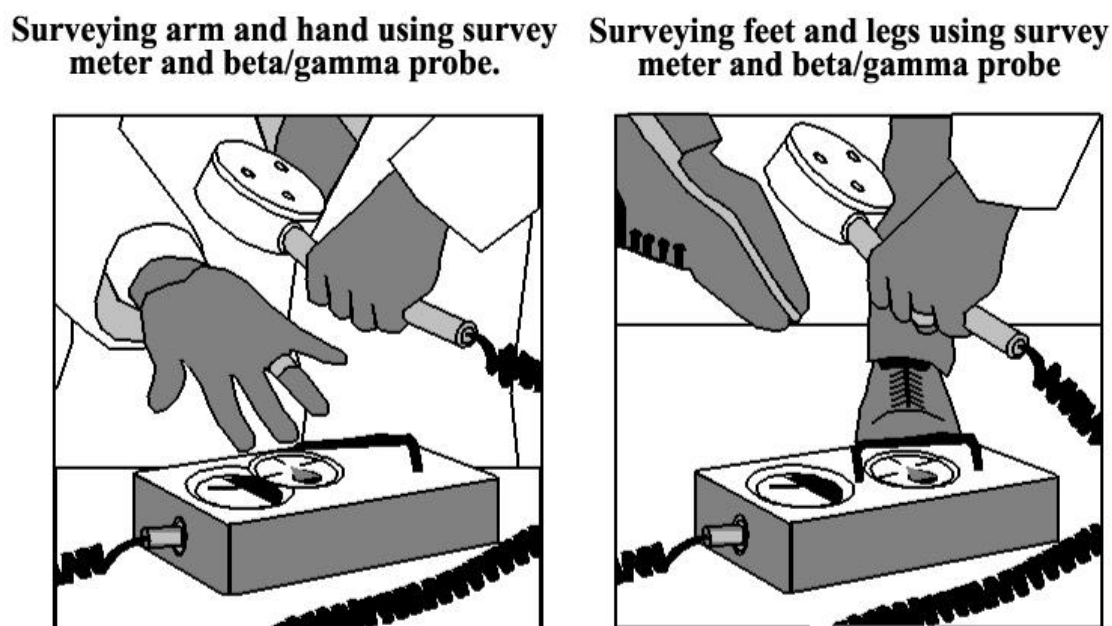


Figure 14: Personnel Surveys. Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the laboratory.

HFS 157.25(1) states that surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the requirements. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form and where operations could expose

workers to the inhalation of radioactive material or where licensed material is or could be released to unrestricted areas;

- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer;
- Bioassays to determine the kinds, quantities or concentration, and in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement (in vivo counting) or by analysis and evaluation of material excreted or removed from the human body; and
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above. (See **Appendix Q**)

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any radiation safety program.

Chapter HFS 157 'Radiation Protection' does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. **Table 12 and 13 in Appendix Q** contain contamination limits that are acceptable to DHFS.

Sealed Source and Plated Foil Leak Test

HFS 157.24 requires the performance of leak tests of sealed and plated foil sources (e.g., GC) at interval not to exceed six months unless otherwise approved by the NRC or an Agreement State and specified by the SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 Ci) of the radioisotope contained in the source or foil.

Manufacturers, consultants, and other organizations may be authorized by DHFS, the NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test

kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the sealed source or plated foil manufacturer's (distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Leak tests are not required if:

- Sources contain only H-3;
- Sources contain only radioactive material with a half-life of less than 30 days;
- Sources contain only a radioactive gas;
- Sources contain 3.7 MBq (100 µCi) or less of beta-emitting or gamma-emitting material or 370 kBq (10 µCi) or less of alpha-emitting material; or
- Sources are stored and are not being used (must be leak tested every 5 years and before use or transfer).

For more information regarding leak tests, see **Appendix R**.

Response from Applicant :

Item 10.7 Surveys (Check all that apply)

- ☐ We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q of WISREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.

IF SEALED SOURCES ARE USED

- ☐ Leak tests will be performed by an organization authorized by DHFS, the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by DHFS, the NRC or an Agreement State to provide leak test kits to other licensees according to kit suppliers instructions.

List the name and license number of organization authorized to perform or analyze leak test (Specify whether DHFS, NRC, or Other Agreement State):

Organization Name _____ License Number _____

Note: An alternate organization may be used to perform or analyze leak test, without amending the license, provided the organization is specifically authorized by DHFS, NRC or an Agreement State.

OR

- ☐ We will perform our own leak testing and sample analysis. We will follow the model procedures in Appendix R of WISREG 'Guidance for Academic, Research and Development and Other Licenses of Limited Scope'.

OR

- ☐ We will submit alternative procedures. (Procedures are attached)

Item 10.8: Transportation

Rule: *HFS 157.06(1); HFS 157.13(15) & (18); HFS 157.21; HFS 157.92(3); HFS 157.93(4-6); HFS 157.94(1); 49 CFR Parts 171-178*

Criteria: Applicants who will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with DHFS and U.S. Department of Transportation (DOT) regulations.

Discussion: Packages shipped by ARDL licensees frequently meet the "Limited Quantity" criteria as described in *49 CFR 173.421*, and therefore could be exempt from certain DOT requirements, but they may be subject to other, less restrictive DOT requirements (e.g., *49 CFR 173.422 and 173.424*; also see **Appendix S** for more information).

If they are not exempted, however, licensed material, including radioactive waste, must be packaged and transported in accordance with DHFS and the DOT requirements if the transportation involves common carriers or the use of public highways. Licensees should develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Licensees should consider the safety of all individuals who may handle or may come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the package integrity is not compromised during transport, and that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of *HFS 157.94(1)*, but are ALARA.

All domestic shipping papers and labels must be in SI units only or must be in SI units first with English units in parenthesis.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in **Chapter HFS 157 ‘Radiation Protection’, Appendix G.**

Response from Applicant :

Item 10.8 Transportation

No response is needed from applicant in this license application, transportation issues will be reviewed during inspections

Reference:

'A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)' can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4900 or by accessing their website at <http://hazmat.dot.gov/pubtrain/ramreview.pdf>.

Item 10.9: Minimization of Contamination

Rule: HFS 157.13(2)

Criteria: Applicants must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. When submitting new applications, applicants should consider the following:

- Implementation of and adherence to good health physics practices in operations;
- Minimization of areas, to the extent practicable, where licensed materials are used and stored;
- Maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill;
- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition;
- Appropriate filtration of effluent streams;
- Use of non-porous materials for laboratory bench tops, flooring, etc.;
- Ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction;
- Use of appropriate plumbing materials with minimal pipelengths and traps; and

- Minimization of the number of disposal sites (sinks) where liquid waste is disposed.

Sealed sources and devices that are approved by the NRC or an Agreement State and located and used according to their SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to DHFS requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant :

Item 10.9 Minimization of Contamination

No response is required if applicant meets the criteria in the following sections: 'Unsealed and/or Sealed Sources', 'Facilities and Equipment', 'Safe use of Radioisotopes and Emergency Procedures', 'Surveys', and 'Waste Management'.

ITEM 10.10: Termination of License

Rule: *HFS 157.13; HFS 157.15; HFS 157.32(8)*

Criteria: Pursuant to the rule requirements described above, the licensee must do the following:

- Notify DHFS, in writing, within 30 days of:
 - Decision to permanently discontinue all activities involving materials authorized under the license.
- Notify DHFS, in writing, within 60 days of:
 - The expiration of its license;
 - A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to DHFS requirements;
 - No principal activities have been conducted at the entire site under the license for a period of 24 months;

- No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to DHFS requirements.
- Submit a decommissioning plan, if required by **HFS 157.13(11)(f)**;
- Conduct decommissioning, as required by **HFS 157.13(11)(j) and HFS 157.13(11)(l)**; and
- Submit to DHFS, a completed DPH Form 45007 ‘*Certificate of Disposition of Materials*’ (**Appendix B**) and demonstrate that the premises are suitable for release for unrestricted use (e.g. results of final survey).
- Before a license is terminated, send the records important to decommissioning to DHFS. If licensed activities are transferred or assigned in accordance with **HFS 157.13(5)(c) 2**, transfer records important to decommissioning to the new licensee.

Discussion: Useful guidance and other aids related to decommissioning are:

- NRC NUREG-1727, ‘*NMSS Decommissioning Standard Review Plan*’ dated September 2000.
- NRC NUREG/BR-0241, ‘*NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses*’, dated March 1997, contain the current regulatory guidance concerning decommissioning of facilities and termination of licenses.
- Appendix B of NRC NUREG/BR-0241 contains a comprehensive list of NRC's decommissioning regulations and guidance. NRC NUREG-1727 contains a list of superseded guidance; however, due to ongoing revisions, applicants are encouraged to consult with DHFS staff regarding updates of decommissioning guidance.
- NRC NUREG-1575, ‘*Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)*’, dated December 1997, should be reviewed by licensees who have large facilities to decommission.
- NRC NUREG-1727 includes a table (Table C2.2) of acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination. NRC NUREG-1727 also contains methods for conducting site-specific dose assessments for facilities with contamination levels above those in the table.

Response from Applicant :

Item 10.10 Termination Of Activities

No response is required from the applicant during the application process. Refer to section titled ‘Termination of Activities’ in WISREG ‘Guidance for Academic Research and Development and Other License of Limited Scope’.

Note: The licensee's obligations are to undertake the necessary decommissioning activities, to submit DPH Form 45007 '*Certificate of Disposition of Materials*' (**Appendix B**), and to perform any other actions as summarized in the 'Criteria'.

Item 11: Waste Management

Rule: *HFS 157.06; HFS 157.13(18); HFS 157.29(4); HFS 157.30*

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Discussion: Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, unusable items contaminated with radioactive material, e.g., absorbent paper, gloves, etc. Licensees may not receive radioactive waste from other licensees for processing, storage or disposal, unless specifically authorized by DHFS.

All radioactive waste must be stored in appropriate containers until its disposal and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. DHFS requires ARDL licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- Decay-in-storage (DIS);
- Release into sanitary sewerage;
- Transfer to an authorized recipient;
- Extended interim storage;
- Disposal of waste as if it were not radioactive (specific wastes);
- Obtaining prior approval of DHFS of any alternate method;
- Release in effluents to unrestricted areas, other than into sanitary sewerage; or
- Incineration.

Licensees may choose any one or more of these methods to dispose of their radioactive waste. Most ARDL facilities store or dispose of radioactive waste by a combination of the first four methods, because of the types and amounts of licensed materials used by these facilities. Applicants wanting to dispose of radioactive waste by incineration should refer to NRC Policy and Guidance Directive PG 8-10, '*Disposal*

of Incinerator Ash as Ordinary Waste dated January 1997. Applicants should note that compliance with DHFS requirements does not relieve them of their responsibility to comply with any other applicable federal, state, or local regulations. Furthermore, some of the radioactive waste may also include additional hazards, (e.g., biohazard or chemical hazard). Such waste is called "mixed waste," and its storage and disposal must also comply with all other applicable federal, state, and local regulatory requirements.

Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. **Chapter HFS 157, 'Radiation Protection'** requires that licensees maintain all appropriate records of disposal of radioactive waste. The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste that, in many instances, may also include radioactive waste. NRC transmitted these guidelines to licensees in NRC IN-94-23, *'Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program'* dated March 1994.

Disposal By Decay-in-storage (DIS)

DHFS has concluded that materials with half-lives of less than or equal to 120 days are appropriate for DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

Applicants should assure that adequate space and facilities are available for the storage of such waste. Licensees can minimize the need for storage space, if the waste is segregated according to physical half-life. Waste containing radioisotopes of physical half-lives within a certain range may be stored in one container and allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container. Procedures for management of such waste should include methods of segregation, surveys prior to disposal, and maintenance of records of disposal. Records should include the date when the waste was put in storage for decay, date when ten half-lives of the longest-lived radioisotope have transpired, date of disposal, and results of final survey before disposal as ordinary trash. Additionally, a procedure for

disposal of radioactive waste by DIS, which incorporates the above guidelines, is provided in **Appendix T**.

Release Into Sanitary Sewerage

HFS 157.30(3) authorizes disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is easily dispersible biological material) in water;
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration specified in **Chapter HFS 157 ‘Radiation Protection’ Appendix E**;
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in **Chapter HFS 157 ‘Radiation Protection’ Appendix E** cannot exceed unity; and
- Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radioisotopes combined.

Licensees are responsible to demonstrate that licensed materials discharged into the public sewerage system are indeed readily soluble in water. NRC IN 94-07, ‘*Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20*’ dated January 1994, provides acceptable criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be "readily dispersible." Careful consideration should be given to the possibility of reconcentration of radioisotopes that are released into the sewer. NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewerage systems in NRC IN 84-94, ‘*Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)*’ dated December 1984.

HFS 157.30(3) is not applicable for releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas pursuant to **HFS 157.23(1)**. However, if licensed material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludges may be required to be disposed of as radioactive waste, using one of the methods described as described in this section of this WISREG.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in *HFS 157.30(3)* and do not exceed the monthly and annual limits specified in **Chapter HFS 157 ‘Radiation Protection’**. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A program for disposal of radioactive waste via sanitary sewer is described in **Appendix T**.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. It is the licensee's responsibility to verify that the intended recipient is authorized to receive the radioactive waste prior to making any shipment. Almost all radioactive waste generated at ARDL facilities consist of low specific activity (LSA) material. The waste must be packaged in approved containers for shipment, and each container must identify the radioisotopes and the amounts contained in the waste. Additionally, packages must comply with the requirements of the particular burial site's license and state requirements. Each shipment must comply with all applicable DHFS and DOT requirements. In some cases, the waste handling contractor may provide guidance to the licensee for packaging and transportation requirements; however, the licensee is ultimately responsible for ensuring compliance with all applicable regulatory requirements.

The shipper must provide all information required in NRC’s Uniform Low-Level Radioactive Waste Manifest, and transfer this recorded manifest information to the intended recipient in accordance with **Chapter HFS 157 ‘Radiation Protection’ Appendix G**. Each shipment manifest must include a certification by the waste generator, as specified in Section II of the appendix. Each person involved in the transfer for disposal and disposal of waste, including waste generator, waste collector, waste processor, and disposal facility operator, must comply with requirements specified in Section III of the above appendix.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers and members of the public. The program should include adequate safety procedures to protect workers, members of the public, and the environment.

Disposal of Specific Waste As If It Were Not Radioactive

The following radioactive wastes may be disposed of as non-radioactive waste:

- Liquid scintillation media (including vials and other items contaminated with liquid scintillation media) containing no more than 1.85 kBq (0.05 μ Ci) of H-3 or C-14 per gram of the medium; and
- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 μ Ci) of H-3 or C-14 per gram averaged over the weight of the entire animal.

Applicants should have procedures that will ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or animals. Applicants must maintain accurate records of these disposals.

Alternate Methods

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

Some licensees do not have an LLW disposal facility available to them and therefore must use on-site interim storage until such time that a facility becomes available. Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site extended interim storage of radioactive waste only as a last resort. The protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it on-site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. Other than DIS, LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC IN 90-09, '*Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees*' dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

Response from Applicant :

Item 11 Waste Management (Check all that apply)

- ☐ We will follow the model waste procedures published in Appendix T of WISREG "Guidance for Academic Research and Development and Other Licenses of Limited Scope."

OR

- ☐ We will follow: ☐ Decay-In-Storage or ☐ Disposal of Liquids Into Sanitary Sewerage waste procedures that are published in Appendix T of WISREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'.

OR

- ☐ We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in Item 11 'Waste Management' of WISREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'. We will contact DHFS for guidance to obtain approval of any method(s) of waste disposal other than those discussed in Item 11 'Waste Management' of WISREG 'Guidance for Academic Research and Development and Other Licenses of Limited Scope'. (Procedures are attached)

OR

- ☐ If access to a radioactive waste burial site is unavailable, we will request authorization for extended interim storage of waste. We will refer to NRC IN 90-09 'Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses', dated February 1990, for guidance and submit the required information with this applications.

NOTE: Applicants do not need to provide information to DHFS if they plan to dispose of LLW via transfer to another authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14 as authorized by s. HFS 157.30(5).

IF SEALED SOURCES ARE USED

- ☐ We will return sealed sources/devices to the manufacturer, distributor or an organization licensed by DHFS, the NRC or another Agreement State.

Note: Information Notices are available at the NRC's website: <http://www.nrc.gov>.

Item 12: License Fees

Rule: *HFS 157.10*

On DPH Form 45016 '*Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope*' (**Appendix A**), enter the fee category and the amount of the fee enclosed with the application.

Response from Applicant :

Item 12 License Fees (Refer to Wisconsin Administration Code s. HFS 157.10)	
Category:	License fee enclosed: <input type="checkbox"/> Yes <input type="checkbox"/> No Amount Enclosed _____

Item 13: Certification

Individuals acting in a private capacity are required to date and sign DPH Form 45016, '*Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope*' (**Appendix A**). Otherwise, representatives of the corporation or legal entity filing the application should date and sign DPH Form 45016, '*Application for Radioactive Material License for Academic, Research and Development and other Licenses of Limited Scope*' (**Appendix A**). Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in 'Management Responsibility,' signing the application acknowledges management's commitment and responsibilities for the radiation protection program. DHFS will return all unsigned applications for proper signature.

Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant. As discussed previously in 'Management Responsibility,' signing the application acknowledges management's commitment and responsibilities for the radiation protection program. DHFS will return all unsigned applications for proper signature.

Response from Applicant :

Item 13 I hereby certify that this application was prepared in conformance with Wisconsin Administrative Code Chapter HFS 157 "Radiation Protection" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.	
SIGNATURE - Applicant Or Authorized Individual	Date signed:
Print Name and Title of above signatory	

Note:

- It is a violation of **Chapter HFS 157 ‘Radiation Protection’**, to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Appendix A:

DPH Form 45016

***Application for Radioactive Material License for
Academic, Research and Development and Other
Licenses of Limited Scope***

To access this form please go to :
<http://www.dhfs.state.wi.us/forms/DPH/dph45016.pdf>

Appendix B:

DPH FORM 45007

Certificate of Disposition of Material

To access this form please go to :
<http://www.dhfs.state.wi.us/forms/DPH/dph45007.pdf>

Appendix C:

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Appendix D:

Gas Chromatography Devices

Gas Chromatography Devices

This appendix may be used as as guidance to request authorization for a GC on an ARDL license.

Note: For use of X-ray Fluorescence Analyzers (XRFs) refer to WISREG-1556, Vol. 1 ‘Guidance for Portable Gauges or XRF Devices.

Rule

Licensees are subject to all applicable provisions of the regulations in **Chapter HFS 157, ‘Radiation Protection’** as they pertain to GC’s.

Information for completing **Items 1 through 4** of the application have already been provided in this WISREG.

Additional information for **Item 4** is requested below.

Item 4: Address(es) Where Licensed Material Will Be Used or Possessed

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown) for each facility at which licensed material will be used or stored. **A Post Office Box address is not acceptable.** In addition, state whether the GC will be used at temporary jobsites.

Item 5: Radiation Safety Officer

Provide the name of the person(s) who will be responsible for the GCs. That person(s) will be specifically named on the license.

If no repair or maintenance on the GC is proposed by the applicant, then no specific training and experience in the use and handling of radioactive materials is necessary for individuals who will use the device(s) or supervise its use. No special training or experience is needed to perform leak tests using a leak-test kit or to clean detector cells used in GC devices, provided the source or foil is not removed from the detector cell.

If the applicant proposes to perform any operations that involve removal of sources containing radioactive material from the device or maintenance and repair of a device that involves the source, then they must ensure a "responsible individual" performs these operations. The responsible individual shall have received instruction and training in the principles and practices of radiation safety, the use of radiation detection instruments, and the performance of these operations. Such training may normally be accomplished in 1 or 2 days. In the application, provide the following information:

- Name of each responsible individual who will perform the operations
- Outline of the instruction and training each responsible individual has received in the principles and practices of radiation safety, the use of radiation detection instruments, and the operations that will be performed, including actual practice in performing the operations. The amount of time spent on each topic in the training should be specified.

Item 7: Training for Individuals Working in or Frequenting Restricted Areas

Persons who will only use a GC under the supervision of the responsible individual named in **Item 6** need no special training and their names do not need to be submitted. These supervised individuals should not be permitted to perform any maintenance or repair operations. Only responsible individuals specifically named in **Item 6** shall perform such operations.

Item 8: Radioactive Material

1. Provide the radioisotopes(s) that will be used in each GC.
2. Provide the manufacturer and model number of the detector cell, foil source, plated source, or sealed source that will be used in each GC.
3. Specify the quantity (activity) of radioactive material that will be in each foil source, plated source, or other sealed source. Provide the number of sources of each foil source, plated source or sealed source that will be possessed, if known. If the total number for each type of source is unknown, provide an anticipated total.

Note: GCs that contain titanium tritide foils or scandium tritide foils require operating temperature control mechanisms and venting to the outside. Provide information on operating temperature controls and venting information with the application, if these kinds of foils are requested in the application.
--

Purpose For Which Licensed Material Will Be Used

Specify the intended purpose for each GC to be used.

Item 9: Facilities and Equipment

HFS 157.13(2) states that an application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and to minimize danger to life or property. *HFS 157.28(1)* also states that licensed material stored in an unrestricted area must be secured from unauthorized removal, and licensed materials in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee.

The room, laboratory, or storage area in which the device is located should be: (1) accessible only to persons authorized to use the device and (2) locked when an authorized person is not physically present. The application should state that the laboratory or area will be locked or secured when an authorized person is not present. The room, laboratory, or storage area cannot be considered a restricted area if it is accessible to unauthorized persons.

Item 10: Radiation Safety Program

10.1 Audit Program

Licensees must review the content and implementation of their radiation protection programs annually, to ensure compliance with DHFS rules and with the terms and conditions of the license. **Appendix L** contains a suggested audit program that is acceptable to DHFS. All areas indicated in **Appendix L** may not be applicable to every licensee and may not need to be addressed during each audit.

10.2 Radiation Monitoring Instruments

A survey meter for routine uses of GCs is not required.

If maintenance and repair operations are proposed as described in **Item 7**, and the operations involve the sealed source, provide information about what surveys will be performed, what type of survey meter will be used for conducting surveys, the range of the survey instrument, and calibration information including

frequency of calibration. It is not necessary to specify the manufacturer and model number of the survey meter. For more information on survey meters, see Item 10.2 'Radiation Monitoring Instruments,' in the main body of this WISREG.

10.3 Material Receipt and Accountability

Licensees are required to maintain records of receipt, transfer, and disposal of licensed material. Loss, theft, or misplacement of licensed material can occur; therefore control and accountability of GCs must be ensured. Licensees who use and/or possess sealed sources are required by license conditions to perform inventories of sealed sources every six months (see sample license, condition no. 16). Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should confirm that these sealed sources have not been disturbed at least every 6 months.

10.4 Occupational Dose

Personnel monitoring devices are not required for the following:

- Routine use and normal operation of GCs; and
- Maintenance and repair operations described in **Item 10.6**, if the radiation source in the GC is in a gaseous form or is nickel-63 (Ni-63).

If proposed uses of GCs include the maintenance and repair operations described in **Item 10.6**, and these operations involve sealed sources other than in gaseous form or Ni-63, an evaluation for personnel monitoring devices is required for persons performing these operations.

The application should indicate that maintenance and/or repair personnel will be provided with either film badges, OSLs or thermoluminescence dosimeters (TLDs) for use while performing service operations or provide a dose evaluation which indicates that personnel will not be required to wear monitoring devices.

10.5 Leak-Testing

DHFS requires testing to determine whether there is any radioactive leakage from sealed/plated foil sources. Records of surveys and leak tests results must be maintained.

When issued, a license will require performance of leak tests of sealed/plated foil sources at intervals as approved by the NRC or an Agreement State and specified by the SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 Ci) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by DHFS, the NRC or an Agreement State either to perform the entire leak test sequence for other licensees or to provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the sealed source or plated foil manufacturer's (distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves. For more information about leak testing sealed/plated foil sources, see 'Surveys,' in the main body of this WISREG.

10.6 Safe Use of Radionuclides and Emergency Procedures

If authorization has been requested to perform maintenance and repair operations then state in the application that the written procedures provided by the device manufacturer will be followed for each such operation requested. If a procedure will be followed other than that provided by the device manufacturer, submit a proposed procedure to use for each operation requested.

10.8 Transportation

If authorization has been requested in the application to use GCs at a temporary jobsite, the applicant must take into consideration DOT regulations, particularly blocking and bracing the device containing licensed material. The applicant is not required to submit transportation information with the application.

10.9 Minimization of contamination

New license applicants are required by *HFS 157.13(2)(b)* to describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Item 11: Waste Management

Because of the nature of the licensed material contained in GC devices, the usual disposal option is to transfer the licensed material to an authorized recipient. State in the application that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it, or provide information for an alternate method of disposal for DHFS review.

Authorized recipients are the original supplier of the device, a commercial firm licensed by DHFS, the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to receive licensed material.

Appendix E:

**Information Needed for Transfer of Control
Application**

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain DHFS's prior written consent before transferring control of the license; some licensees refer to this as "transferring the license." Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. The new name of the licensed organization. If there is no change, the licensee should so state.
2. The new licensee contact and telephone number(s) to facilitate communications.
3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.
4. An indication of whether the transferor will remain in non-licensed business without the license.
5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.
6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).
7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.
8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.
9. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.
10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to **HFS 157.15**; public dose, waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to DHFS for license terminations.
11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If

not, does the successor company agree to assume full liability for the decontamination of the facility or site?

12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in **HFS 157.15**. Include information about how the transferee and transferor propose to divide the transferor's assets, and responsibility for any cleanup needed at the time of transfer.
13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to DHFS by the transferor. These include, but are not limited to: maintaining decommissioning records required by **HFS 157.15**; implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with DHFS before license transfer.

14. Documentation that the transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.
15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and rules.

Reference: See the NRC website at: www.nrc.gov to obtain copies of NRC Information Notice 89-25, Revision 1, '*Unauthorized Transfer of Ownership or Control of Licensed Activities*.'

Appendix F:

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Appendix G:

Guidance on Decommissioning Funding Plan and Financial Assurance

Table 7 and 8 are used to determine the need for certification of financial assurance (F/A) for decommissioning or a decommissioning funding plan (DFP), as required by *HFS 157.15*. **Table 7** is a listing of isotopes with a half-life of greater than or equal to 120 days. If the applicant proposes to use isotopes with a half-life greater than or equal to 120 days, divide the requested possession limit (in mCi) of the isotope by the value for that isotope in **Table 7**. If the material requested is in an unsealed form, use the value in the unsealed column. If the material requested is in an sealed form, use the value in the sealed column. Place the fraction in the proper column in worksheet **Table 8**. Add the fractions in the column and place the total in the row labeled total (i.e., "sum of the ratios").

Table 7: Isotopes With Half-lives Greater Than or Equal to 120 Days

Isotope	Unsealed (Ci)	Sealed (Ci)
americium-241	10	1 x 10 ⁸
antimony-125	10000	1 x 10 ¹¹
barium-133	10000	1 x 10 ¹¹
cadmium-109	10000	1 x 10 ¹¹
calcium-45	10000	1 x 10 ¹¹
carbon-14	100000	1 x 10 ¹²
Cerium-144	1000	1 x 10 ¹⁰
Cesium-134	1000	1 x 10 ¹⁰
Cesium-135	10000	1 x 10 ¹¹
Cesium-137	10000	1 x 10 ¹¹
Chlorine-36	10000	1 x 10 ¹¹
Cobalt-60	1000	1 x 10 ¹⁰
Europium-152 (13 yr)	1000	1 x 10 ¹⁰
Europium-154	1000	1 x 10 ¹⁰
europium-155	10000	1 x 10 ¹¹
gadolinium-153	10000	1 x 10 ¹¹
gold-198	100000	1 x 10 ¹²
hydrogen-3	1000000	1 x 10 ¹³
indium-115	10000	1 x 10 ¹¹
iodine-129	100	1 x 10 ⁹
iron-55	100000	1 x 10 ¹²
krypton-85	100000	1 x 10 ¹²
manganese-54	10000	1 x 10 ¹¹
nickel-59	100000	1 x 10 ¹²
nickel-63	10000	1 x 10 ¹¹
niobium-93m	10000	1 x 10 ¹¹
platinum-193	100000	1 x 10 ¹²
polonium-210	100	1 x 10 ⁹
promethium-147	10000	1 x 10 ¹¹
rubidium-87	10000	1 x 10 ¹¹
ruthenium-106	1000	1 x 10 ¹⁰
silver-110m	1000	1 x 10 ¹⁰
strontium-90	100	1 x 10 ⁹

Appendix H:

**Considerations for Laboratory Animal and
Veterinary Medical Uses**

This appendix provides additional information on the use of radioactive materials in laboratory animals, in animals used for research in the environment, and by veterinarians.

I. AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

HFS 157.21(2) requires that licensees use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material, and should ensure that the facility and equipment are adequate for safe use. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Officer (RSO).

For example, a licensee may establish release criteria for cats treated with iodine-131 of 0.5 millirem/hour at one foot from the surface of the body closest to the thyroid. This would involve confining the cats at the veterinary facility until the dose rate falls to that level. This will ensure that persons caring for the cat after discharge will not be exposed to more than 100 millirem [see *HFS 157.23(1)(a)I*] as long as direct contact with the cat is restricted to less than 2 hours a day.

If minor children or a pregnant woman reside(s) in a home where a cat is proposed for treatment, serious consideration should be given to confining the animal until the measurement at the thyroid is less than 2 millirem/hour. As a margin of safety, pet owners should be instructed to minimize direct contact with their cat.

II. LICENSEE'S FACILITY DESIGN

Facility design considerations for hot labs, animal confinement and waste storage areas.

- Restricted access to hot lab, waste storage, and confinement areas;
- Hot lab located near confinement area;
- Confinement area with dedicated ventilation;
- Stainless steel metabolic cages (easily decontaminated) should be used;

- Shielding will be provided as needed;
- Concrete floors, no drains, in confinement area;
- Continuous negative pressure ventilation in confinement area (for volatile RM); and
- Evaluation of air concentration of radioactive materials in confinement area.

III. LABORATORY ANIMALS

A. Training

Before allowing an individual to care for animals used in studies with or treated with licensed material, the Radiation Safety Officer (RSO), Authorized User (AU), and/or veterinarian must ensure that the individual has sufficient training and experience to maintain doses ALARA, control contamination, handle waste appropriately, etc.

Classroom training may be in the form of lecture, videotape, or self-study and should cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training should consist of:

- Observing authorized personnel using survey equipment, using proper contamination control techniques, and proper disposal of radioactive material; and
- Using survey equipment, proper contamination control techniques, and proper disposal of radioactive material procedures under the supervision of, and in the physical presence of, an individual authorized to handle animals treated with licensed material or otherwise containing licensed material.

B. Contamination Control and Waste Handling

In order to minimize the spread of contamination, animals used in studies with or treated with licensed material should be housed in cages or stalls separate from other animals. The facilities, stalls, or cages

shall be secured to prevent unauthorized access to the animals. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, and eye protection, as appropriate.

Special care should be observed when cleaning the cage or stall. The cage or stall, the bedding, and waste from the animal may contain radioactive material. Any radioactive material should be properly disposed of as described in **Item 11**, '*Waste Management*.'

Disposal of laboratory animals that contain radioactive material requires special procedures. Animal carcasses that contain less than 1.85 kBq/gram (0.05 microcuries/gram) of carbon-14 or hydrogen-3 may be disposed of by the same method as non-radioactive animal carcasses. Animal carcasses that contain radioactive material with a half-life of less than 120 days may be allowed to decay-in-storage in a freezer dedicated for radioactive material. Animal carcasses must be held for a minimum of 10 half-lives of the longest-lived isotope. After 10 half-lives, the animal carcasses may be disposed as non-radioactive, if radiation surveys (performed in a low background area and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background (See **Item 11**, '*Waste Management*').

C. Radiation Safety Procedures for the Care and Handling of Animals Administered Radioactive Material

1. Only trained individuals shall be involved in the care and handling of animals that have been administered radioactive materials.
2. The door(s) to animal housing areas shall be locked at all times when animals are present. Only authorized personnel trained in radiation safety shall have access to these areas.
3. The door(s) to animal housing areas, and each cage containing a radioactive animal, shall be conspicuously posted with a "Caution Radioactive Material" sign.
4. Authorized personnel must record the appropriate information and sign the log near the door each time they enter or leave the animal housing area.
5. Personnel providing care to animals shall wear lab coats, disposable gloves (and boots, if appropriate), and whole body dosimeters (extremity dosimeters may also be required).
6. Disposable gloves and boots shall be removed at the entrance and placed in a radioactive waste container before leaving the housing area. Hands, feet, and clothing shall be checked for contamination at this time using a portable survey meter.

7. Animals shall be fed and watered using disposable dishes that will be placed, after use, in the radioactive waste container.
8. Animal excreta shall be collected daily, sealed in plastic bags, properly labeled, and frozen (if necessary). Excreta may not be disposed of as normal waste until the radiation levels from it have reached background.
9. Adequate precautions must be employed for the transfer of treated animals through unrestricted areas to prevent contamination of these areas by excreta.
10. In case of animal death, the carcass must be frozen and stored as radioactive waste until its radiation levels have reached background.
11. A radioactive contamination survey of the housing area shall be performed each day during which an animal is housed.
12. The animal housing area shall not be used for other purposes until surveys indicate that it is free of contamination.

D. Animals Used for Research in the Environment

Before a researcher releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the researcher will ensure that the dose that members of the public will receive from the animal is within limits of *HFS 157.23(1)*. *HFS 157.23(1)* requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Further, the researcher may be required to perform an assessment of the impact the radioactive material will have on the environment (See the section titled '*Purpose(s) for Which Licensed Material Will Be Used*' in **Item 8 'Radioactive Material'**).

IV. VETERINARY MEDICAL USE

A. Training

DHFS believes that to demonstrate adequate training and experience, the veterinarian should have training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles;

- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of radioactive material to be used); and
- Hands-on Use of Radioactive Materials.

The length of the training (usually 40 hours) will depend upon the type, form, quantity and proposed use of the licensed material requested, but training shall cover the subjects stated.

B. Responsibilities of Veterinarians

The following list describes the responsibilities of veterinarians intending to use iodine-131 in felines.

- Patient selection;
- Evaluation of owner cooperation;
- Dose estimate;
- Dose administration;
- Patient confinement during therapy;
- Waste handling during confinement;
- Applying patient discharge criteria;
- Owner instruction for post-discharge care; and
- Patient follow-up.

C. Criteria for Patient Selection Prior to Radioiodine Administration for Veterinary Feline Therapy

Veterinarians should consider the following in their patient selection criteria. They should also perform and document the required counseling and consideration of extended confinement when minor children or a pregnant woman reside(s) in the home.

- Cats must be referred by a practitioner who has clinically documented hyperthyroidism in the cat.
- Cats should be in otherwise good health - no congestive heart failure, chronic renal failure, or other serious health problems.

- Cats belonging to owners who exhibit anxiety about radioactive material should not be accepted for treatment.
- Owners must agree to be separated from the cat for up to two weeks during therapy confinement.
- Owners must sign a consent form confirming that post-therapeutic procedures will be followed.
- Owners with minor children or pregnant women living in the home will be carefully evaluated before a cat is selected for treatment. If a decision is made to treat, detailed counseling will be given about avoiding contact between the treated animal and these individuals. Consideration should be given to extending the confinement of the animal until the exposure rate at the body surface closest to the thyroid is less than 2 millirem per hour. Such counseling and consideration must be documented.

D. Contamination Control and Waste Handling

See ‘*Contamination Control and Waste Handling*’ in **Section III, B** above.

E. Release of Animals from a Licensee's Facility

Before a veterinarian releases an animal that has been injected with a radiopharmaceutical or has had radioactive seeds implanted, the veterinarian must ensure that the dose that members of the public (including the animal's caretaker) will receive from the animal is within limits of **HFS 157.23(1)**. **HFS 157.23(1)** requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Furthermore, licensees should provide instructions to the animal's caretaker to keep doses ALARA.

F. Instructions to Animal Caretaker Upon Release

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. The instructions should not, however, interfere with or contradict the best medical judgment of the veterinarian. The instructions should include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

G. Examples of Owner Information, Consent Form, and Caretaker Instructions

1. Owner Information and Consent Form

EXAMPLE OWNER INFORMATION AND CONSENT FORM

Radioactive iodine has been used to treat hyperthyroidism in people for over fifty years. The first reported use of radioactive iodine to treat hyperthyroid cats was in 1983. Radioactive iodine therapy is a safe and effective choice for treating hyperthyroidism in most cats.

The cat does not experience any adverse side effects from the radioactive iodine. Because the delivery of radiation is targeted to the overactive thyroid gland, the cat does not experience any radiation side effects at the normal therapy doses used to treat hyperthyroidism. The medicine is given as an injection, usually on the day the cat is admitted to the clinic. Following the treatment, the cat will be hospitalized for 5-14 days to allow most of the radioactive medicine to leave the thyroid gland or decay prior to discharge from the clinic. This is different from the situation in human nuclear medicine as most people treated with radioactive iodine for hyperthyroidism are discharged the same day they are treated.

You cannot visit your pet during therapy, nor can pets be removed from the ward until officially released. You cannot terminate therapy or arrange for early release once therapy has begun. Pets may not be boarded/hospitalized elsewhere until they meet the requirements for release.

After being released from therapy, your cat will still possess a very low level of radioactivity, being voided out primarily via urine and feces. You don't need to totally isolate your cat from people/pets, but you must follow safety precautions until the date listed on the next page. Due to the natural decay of radioactivity and continual loss of radioiodine through the urine and stool, your cat will contain no detectable level of radioactivity soon after that date.

During hospitalization, cats are housed in individual enclosures in an isolation room in the clinic. Bedding is changed regularly and fresh food and water are available at all times. Cats get plenty of attention while they are hospitalized. Please be sure to let us know if your cat has any special feeding requirements so that his/her stay can be made as comfortable as possible.

Within one to three months after therapy, 85-90% of hyperthyroid cats become normal (euthyroid), 5-7% will become hypothyroid (too little thyroid hormone in the blood) and may require oral thyroid hormone replacement therapy, and 5-7% remain somewhat hyperthyroid. Cats with persistent hyperthyroidism can be retreated three months after their initial therapy.

To be candidates for radioactive iodine therapy, all cats have screening laboratory work (CBC/Chem screen, diagnostic T4, and urinalysis) performed by the referring veterinarian within one month prior to the anticipated treatment date. We must have copies of this lab work before your cat comes for treatment. Cats with chronic renal (kidney) failure and/or advanced heart disease are not good candidates for radioactive iodine therapy.

Please let us know what medications your cat is receiving, as some medications may interfere with radioactive iodine therapy. If your cat is receiving oral anti-thyroid medication (such as Tapazole or Methimazole), it will need to be discontinued _____ days prior to therapy with radioactive iodine. If your cat requires other medication, we will continue to administer it during your cat's hospitalization.

Please read the radiation safety instructions and consent form. Feel free to discuss any questions or concerns. If you are unable/unwilling to comply with these precautions, you should consider surgical or medical management of your cat's condition.

EXAMPLE OWNER INFORMATION AND CONSENT FORM

Your pet was treated with ____ millicuries of radioactive iodine on _____.
When released to your care, your pet had an exposure rate of ____ millirem per hour at one foot from its thyroid gland.

NO SPECIAL SAFETY PRECAUTIONS ARE NEEDED AFTER

Date: _____

The medication your cat has received is beneficial to the cat, but it is important that other persons not be unnecessarily exposed to radiation. With the release of the patient to your care, you are accepting responsibility for the radiation protection of yourself and all other persons who come into contact with your pet. Your cooperation is needed to comply with the laws of the State of Wisconsin and to allow continued availability of this type of treatment. Please feel free to contact us regarding any specific problem or questions you may have regarding your pet's treatment or these radiation safety instructions.

1. Keep the cat confined to your home. Area wildlife, neighbors, their children and pets, are unaware of the radioactivity in its urine or feces.
2. Limit close contact (closer than one foot) to less than 10 minutes per day. Avoid prolonged face-to-face snuggling and face/hand contact with your cat's saliva and footpads.
3. Wash your hands thoroughly after handling your cat, its food dishes, or litter pan.
4. Do not allow your cat to sleep on your bed. Keep your cat in an unoccupied room at night.
5. Put a plastic liner in box before adding litter (if cat shreds liner, don't use it but discard box after date listed above). Keep box out of occupied areas and away from unsupervised dogs and children.

A. FOR PUBLIC SEWER: Add flushable litter to box, scoop soiled litter into toilet and flush. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.

B. FOR SEPTIC SYSTEM: Scoop soiled litter into a ziploc bag and seal. Place this bag into a second ziploc bag and seal. Discard into a covered trash can outside of your home. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.

C. IF YOU DO NOT USE SCOOPABLE LITTER: Change the litter at least every other day by removing it in the liner. Seal the liner and discard into a covered trash can outside of your home. After the date listed above, discard any remaining soiled litter into the trash. Hold all soiled litter for an additional two weeks after the release date listed above, then send to a landfill.

NOTE: Most landfills do not allow the disposal of low-level radioactive waste until the radioactivity has decayed to nearly background levels. Many solid waste disposal facilities have installed radiation detectors at entrance(s) to prevent the disposal of radioactive material at landfills. If the detectors indicate there is radioactive material in the waste truck, the waste disposal facility staff or a contractor must

search the truck and remove the radioactive material, which is a costly and a time-consuming process. Therefore, it is important that you hold the litter for the recommended period of time in order to satisfy this requirement.

6. If your cat vomits/soils outside the litter box, use normal cleaning procedures. Seal all soiled paper cleaning materials in a ziploc bag. Place this bag into a second ziploc bag, seal and put in outside trash with soiled litter. Wash hands thoroughly.

7. Anyone pregnant or younger than 18 should not handle the soiled litter.

8. Keep your cat away from food preparation areas.

9. Instruct children to avoid the cat, and wash their hands if they touch it. Small children may not remember or understand these rules, so take extra precautions by having them wash their hands often, especially before eating.

10. If your pet must be seen by a veterinarian prior to the release date listed on this form, please inform the doctor of the type of treatment that your cat received and the date it was treated. Show this form to the doctor prior to the examination.

11. If your pet should die prior to the date listed on this form, please notify

Dr. _____ at _____.
(veterinarian) (phone)

I have read this form and the information contained in it has been explained to me. I understand the radiation safety precautions that I must follow until the date listed above.

Owner's Signature _____ Date _____

Veterinarian's Signature _____ Date _____

2. Caretaker Instructions

Sample Instructions to Caretakers of Animals Administered Radiopharmaceuticals or Other Unsealed Materials

Radiopharmaceutical instructions, to the caretaker, should include the following topics:

- Maintaining distance from people;
- Minimizing time in public places (e.g., walks on public sidewalk, parks, beaches, grooming salon);
- Precautions to reduce the spread of radioactive contamination, including animal excreta (which may need to be held for decay)¹; and
- The length of time each of the precautions should be in effect.

Example Radiopharmaceutical Instructions

The animal has been treated with radioactive material (isotope) and still possesses a low level of radioactivity. The present level of radioactivity is below the regulatory agency level necessary for isolating the animal from humans. Because some radioactivity will be present for the next few days, it is necessary that the following safety precautions be exercised for the next _____ days:

1. The animal should be kept inside or in his/her cage/stall following hospital discharge.
2. The animal should not be permitted to have prolonged contact with children under the age of 18 for _____ days following hospital discharge. Close contact should be limited to less than _____ minutes per day.
3. Pregnant women should avoid ALL contact with the animal or its urine and/or feces for at least _____ days after discharge.
4. Family members should not be permitted to sleep with the animal for _____ days after discharge. They also should limit close contact with the animal (being within 1 meter or 3 feet of the animal) for the next _____ day(s) to no more than _____ minutes a day. Preferably, contact with the animal should be kept to a distance of more than 1 meter or 3 feet for this period.
5. Use plastic litter pan liners and a scoopable litter (for cats).
6. Disposable gloves should be worn whenever changing the litter box for the next _____ days after discharge.
7. Wash hands after contact with the animal or the litter.
8. Call _____ to discuss any other radiation safety concerns.

¹ Many solid waste disposal facilities have installed radiation detectors at entrance(s) to prevent the disposal of radioactive material at landfills. If the detectors indicate that there is radioactive material in the waste truck, the waste disposal facility staff or a contractor must search the truck and remove the radioactive material, which is a costly and time-consuming process. Although it is proper to dispose of animal excreta in a landfill, caretakers should consider storing animal excreta in a remote location to allow the radioactive material to decay. If applicable, caretakers should contact the veterinarian for further information about the length of time that animal excreta should be held for decay.

Sample Instructions to Caretakers of Animals Implanted with Sealed Sources

A small radioactive source has been placed (implanted) inside the animal. The source is actually many small metallic pellets or seeds, which are each about 1/4" to 1/3" long, similar in size and shape to a grain of rice. The following precautions should be taken for ____ days, to minimize exposure to radiation to humans from the source inside the animal:

- Stay at a distance of ____ feet from ____;
- Maintain separate sleeping arrangements;
- Minimize the animal's time with children and pregnant women;
- Do not hold or cuddle pet;
- Avoid taking the animal on public transportation; and
- Examine any bandages that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

If a seed or pellet has fallen out, do the following:

- Do not handle it with fingers. Use something like a spoon or tweezers to place it in a jar or other container that can be closed with a lid; and
- Place the container with the seed or pellet in a location away from people.

Telephone _____ at _____.

Appendix I:

Radiation Safety Officer Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with DHFS and DOT regulations and the conditions of the license; see **Figure 3**. Typically, these duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of radioactive material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in *HFS 157.23(1)*.
- Ensure security of radioactive material.
- Posting of documents as required by *HFS 157.88*.
- Ensure that licensed material is transported in accordance with applicable DHFS and DOT requirements.
- Ensure that radiation exposures are "ALARA."
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with DHFS and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to **Chapter HFS 157 'Radiation Protection'**.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, rules, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license.

- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by *HFS 157.06(1)*, *HFS 157.13(18)* and *HFS 157.15(7)*.
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all users are properly trained.
- Perform annual audits of the radiation safety program to ensure that the licensee is complying with all applicable DHFS requirements and the terms and conditions of the license (e.g., leak tests, inventories, use limited to trained, approved users, etc.), the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are “ALARA” in accordance with *HFS 157.21* and required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of “ALARA” or *HFS 157.22 & 23* limits are investigated and reported to DHFS and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and up-to-date copies of **Chapter HFS 157 ‘Radiation Protection’**, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to DHFS during the licensing process.

Appendix J:

Radiation Safety Training Topics

This appendix is intended only as a guide for developing a training program. Individuals working with radioisotopes may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be provided by providing a simple hand-out, whereas others may require extensive training, including a written exam to assess retention of the topics presented.

Frequency of Training

- A. Before assuming duties with, or in the vicinity of, radioactive materials
- B. Whenever there is a significant change in duties, DHFS rule, or the terms of the license
- C. Annually (refresher training)

General Information

- A. Radiation safety
 - 1. radiation vs. contamination
 - 2. internal vs. external exposure
 - 3. biological effects of radiation
 - 4. ALARA concept
 - 5. use of time, distance, and shielding to minimize exposure.
- B. Regulatory requirements
 - 1. RSO
 - 2. material control and accountability
 - 3. personnel dosimetry
 - 4. radiation safety program audits
 - 5. transfer and disposal
 - 6. record keeping
 - 7. surveys
 - 8. postings
 - 9. labeling of containers
 - 10. handling and reporting of incidents or events
 - 11. licensing and inspection by DHFS
 - 12. need for complete and accurate information
 - 13. employee protection

14. deliberate misconduct.

Licensee-Specific Program Elements

- A. Authorized users and supervised users
- B. Ordering and receiving radioisotopes
- C. Applicable DHFS requirements and license conditions
- D. Areas where radioactive material is used or stored
- E. Potential hazards associated with radioactive material in each area where the individuals will work
- F. Appropriate radiation safety procedures
- G. Licensee's in-house work rules. (For instructions on laboratory safety and uses of radioisotopes, see '*For Laboratory Safety and Use of Radioisotopes*' below.)
- H. Each individual's obligation to report unsafe conditions to the RSO
- I. Appropriate response to spills, emergencies or other unsafe conditions
- J. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable
- K. Locations where the licensee has posted or made available: notices, copies of pertinent DHFS rule, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by **HFS 157.88**.
- L. Emergency procedures:
 - 1. RSO name and telephone number
 - 2. immediate steps to prevent or control spread of contamination
 - 3. clean-up instructions, decontamination.
- M. Survey program:
 - 1. survey instrument accessibility
 - 2. who is responsible
 - 3. types, contamination and area
 - 4. frequency
 - 5. levels of contamination
 - 6. personnel, hands, shoes
 - 7. records
- N. Waste
 - 1. liquid
 - 2. solids
 - 3. sanitary sewer
 - 4. burial (transfer to low level waste repository)

5. storage
 6. decay-in-storage
 7. waste storage surveys
 8. incineration
 9. records
- O. Dosimetry
1. whole body
 2. extremities
 3. lost or replacement badges and dose assessment
 4. bioassay procedures
 5. records
- P. Instrumentation
1. survey meters-use, calibration frequency, use of check sources
 2. analytical instruments-gas chromatographs, liquid scintillation counters
- Q. Procedures for receiving packages containing radioactive materials
1. normal
 2. off-duty
 3. notification of user and RSO
 4. security
 5. exposure levels
 6. possession limit
 7. receipt of damaged packages
- R. Procedures for opening and examining packages
1. leakage and contamination
 2. monitoring packages
 3. monitoring packing materials
 4. gloves
 5. transferring material to users
- S. Animal experiments
1. description of facilities
 2. safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages
 3. security
- T. Sealed sources
1. leak test requirements

- 2. inventory requirements
- 3. exempt quantities
- 4. records
- U. Other topics, as applicable
- V. Question and answer period

For Laboratory Safety and Use of Radioisotopes

- A. Control procedures for obtaining permission to use radioactive materials at the facility; give limitations on quantity to be handled per user, allowed per experiment, etc.
- B. Protective clothing and what laboratory apparel to wear and what equipment to use.
- C. Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. As an example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or gloveboxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma emitting licensed materials are handled.
- D. Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.
- E. Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel.
- F. Decontamination procedures to use and whom to contact in case of an emergency.
- G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.
- H. Requirements for storage, labeling of containers, and identification of areas where licensed materials are used.
- I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.
- J. Waste disposal procedures to follow limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.
- K. Records to be maintained on use and disposal of licensed materials.
- L. Prohibition of pipetting by mouth, eating, smoking, and drinking in areas where licensed materials are used.

Appendix K:

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that an ARDL licensee will use or otherwise have available. Not every ARDL applicant will need to address each topic in its application.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in **Chapter HFS 157 ‘Radiation Protection’ Appendix E**. Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.

- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.

- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of ***HFS 157.27***.
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per ***HFS 157.22***.

Appendix L:

Sample Audit Program

An audit is conducted, in part, to fulfill the requirements of *HFS 157.21* for an annual review of the content and implementation of the licensee's radiation protection program. It should also identify program weaknesses and allow licensees to take early corrective actions (before a DHFS inspection). During an audit, the auditor needs to keep in mind not only the requirements of DHFS's requirements but also the licensee's commitments in its applications and other correspondence with DHFS. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement.

The form in this appendix can be used to document the annual audit of the radiation protection program. Guidance follows on completing each section of the form. In the "remarks" portions of the form, note any deficiencies that were identified and the corrective actions taken (or to be taken).

Section 1: Audit History. Enter the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.

Section 2: Organization and Scope of Program. Give a brief description of the organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in the license and fulfills the duties specified in the license.

Section 3: Training, Retraining, and Instructions to Workers. Ensure that workers have received the training required by *HFS 157.88(2)*. Be sure that, before being permitted to use radioactive material, the user has received training and has a copy of the licensee's safe use and emergency procedures. Note: whether refresher training is conducted in accordance with licensee commitments. Ensure that each worker has a copy of the licensee's procedures, and by interview and/or observation of selected workers that he/she can implement them.

Section 4: Audits. Verify that audits fulfill the requirements of *HFS 157.21*, are conducted in accordance with licensee commitments, and are properly documented.

Section 5: Facilities. Verify that the licensee's facilities are as described in its license documents.

Section 6: Materials. Verify that the license authorizes the quantities and types of radioactive material that the licensee possesses.

Section 7: Leak Tests. Verify that all sealed/plated foil sources are tested for leakage at the prescribed frequency in accordance with *HFS 157.24*. Records of results should be maintained.

Section 8: Inventories. Verify that inventories are conducted at least once every 6 months to account for all sources; inventory records should be maintained.

Section 9: Radiation Surveys. Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are calibrated (at the required frequency) in accordance with license conditions and in accordance with *HFS 157.31(3)*. Calibration records must be retained for 3 years after the record is made. Check that radiation levels in areas adjacent to use are within regulatory limits and in accordance with *HFS 157.25(1)*. Verify compliance with *HFS 157.23(1)*. Records of surveys must be retained for 3 years after the record is made.

Section 10: Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing radioactive material, received from others, are received, opened, and surveyed in accordance with *HFS 157.29(6)*. Ensure that transfers are performed in accordance with *HFS 157.13(15)*. Records of surveys, receipt, and transfer must be maintained in accordance with *HFS 157.06(1)*; *HFS 157.13(18)*; and *HFS 157.31(3)*.

Section 11: Transportation. Determine compliance with Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with **Chapter HFS 157 ‘Radiation Protection’, Subchapter XIII ‘Transportation’** requirements. Verify that shipping papers are prepared, that they contain all needed information, and that they are readily accessible during transport.

Section 12: Personnel Radiation Protection. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. If personnel dosimetry is provided or required, verify that it complies with *HFS 157.25(1)* and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with *HFS 157.22(8)*. Check whether records are maintained as required by *HFS 157.31*.

Section 13: Auditor's Independent Measurements (If Made). The auditor should make independent survey measurements and compare the results with those made or used by the licensee.

Section 14: Notification and Reports. Check on the licensee's compliance with the notification and reporting requirements in *HFS 157.13(17)* and *HFS 157.23*. Ensure that the licensee is aware of DHFS telephone numbers: during normal business hours (7:30 a.m. until 4:30 p.m.) at (608) 267-4797 and for after hour emergencies at (609) 258-0099.

Section 15: Posting and Labeling. Check for compliance with the posting and labeling requirements of *HFS 157.88(1)* and *HFS 157.29(2) & (4)*.

Section 16: Recordkeeping for Decommissioning. Check to determine compliance with *HFS 157.15(7)*.

Section 17: Information Notices. Check to determine if the licensee is receiving information notices from DHFS. Check whether the licensee took appropriate action in response to DHFS mailings.

Section 18: Special License Conditions or Issues. Verify compliance with any special conditions on the licensee's license. If the licensee has any unusual aspect of its work, review and evaluate compliance with regulatory requirements.

Section 19: Continuation of Report Items. This section is self-explanatory.

Section 20: Problems or Deficiencies Noted; Recommendations. This section is self-explanatory.

Section 21: Evaluation of Other Factors. Evaluate licensee management's involvement with the radiation safety program, whether the RSO has sufficient time to perform his/her duties, and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Sample Checklist

Audit Report No.: _____ License No.: _____

Date of this Audit: _____

Licensee's name and mailing address:

Audit of activities at (Address):

Contact at Audit Location: _____

Telephone No.: _____

Summary of Findings and Action:

☐ No deficiencies

☐ Deficiencies

☐ Action on previous deficiencies

Recommendations:

Auditor: _____

(Signature)

Date: _____

1. AUDIT HISTORY

☐ N/A (N/A means "Not applicable" - Initial Audit)

A. Last audit of this location conducted _____

B. Problems/deficiencies identified during last two audits or two years, whichever is longer

☐ YES ☐ NO

C. Open problems/deficiencies from previous audits:

Status Requirement	Prob./Def.	Corrective Action Taken (Y/N)	Open/Closed
--------------------	------------	-------------------------------	-------------

D. Any previous problem/deficiency not corrected or repeated
Explain:

☐ YES ☐ NO ☐ N/A

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure:

1. Structure is as described in license documents

☐ YES ☐ NO

2. Multiple authorized locations of use

☐ YES ☐ NO

3. Briefly describe scope of activities involving radioactive material, frequency of use, staff size, etc

B. Radiation Safety Officer

1. Authorized on license

☐ YES ☐ NO

2. Fulfills duties as RSO

☐ YES ☐ NO

C. Use only by authorized individuals

☐ YES ☐ NO

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers per **HFS 157.88(2)**

☐ YES ☐ NO

B. Training program required

☐ YES ☐ NO

C. Training records maintained

☐ YES ☐ NO

D. Evaluation of individuals' understanding of procedures and rules based on interviews, observation of selected workers

☐ YES ☐ NO

1. Each has an up-to-date copy of the licensee's safe use and emergency procedures

☐ YES ☐ NO

2. Adequate understanding of:

a. Current safe use procedures

☐ YES ☐ NO

b. Emergency procedures

☐ YES ☐ NO

E. Workers cognizant of requirements for:

1. Radiation Safety Program **HFS 157.21**

☐ YES ☐ NO

2. Annual dose limits **HFS 157.22 & 23**

☐ YES ☐ NO

3. DPH forms: "Cumulative Occupational Exposure History" and "Occupational Exposure Record for a Monitoring Period"

☐ YES ☐ NO

4. 10% monitoring threshold **HFS 157.25(2)**

☐ YES ☐ NO

5. Dose limits to embryo/fetus and declared pregnant women **HFS 157.22(8)**

☐ YES ☐ NO

6. Procedures for opening packages **HFS 157.29(6)**

☐ YES ☐ NO

Remarks:

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

A. Audits are conducted

☐ YES ☐ NO

1. Audits conducted by _____

2. Frequency _____

B. Content and implementation of the radiation protection program reviewed annually **HFS 157.21**

☐ YES ☐ NO

C. Records maintained per **HFS 157.31(2)**

☐ YES ☐ NO

5. FACILITIES

A. Facilities as described in license application

Remarks:

6. MATERIALS

A. Isotopes, quantities, and use as authorized on license

☐ YES ☐ NO

Remarks:

7. LEAK TESTS

A. Leak test performed as described in correspondence with DHFS (consultant; leak test kit; licensee performed)

☐ YES ☐ NO

B. Frequency: every 6 months or other interval, as approved by the NRC or an Agreement State

☐ YES ☐ NO

C. Records with appropriate information maintained

☐ YES ☐ NO

Remarks:

8. INVENTORIES

A. Conducted at 6-month intervals

☐ YES ☐ NO

B. Records with appropriate information maintained

☐ YES ☐ NO

Remarks:

9. RADIATION SURVEYS

A. Instruments and Equipment:

1. Appropriate operable survey instrumentation possessed or readily available

☐ YES ☐ NO

2. Calibrated as required **HFS 157.25(1)**

☐ YES ☐ NO

3. Calibration records maintained **HFS 157.31(3)**

☐ YES ☐ NO

B. Briefly describe survey requirements **HFS 157.25(1)**:

C. Performed as required **HFS 157.25(1)**

1. Radiation levels within regulatory limits

☐ YES ☐ NO

2. Corrective action taken and documented

☐ YES ☐ NO

D. Records maintained **HFS 157.31(3)**

☐ YES ☐ NO

E. Protection of members of the public

1. Adequate surveys made to demonstrate either (a) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 100 mrem in a year **HFS 157.23(1)**

☐ YES ☐ NO

2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour **HFS 157.23(1)**

☐ YES ☐ NO

3. Records maintained **HFS 157.31(8)**

☐ YES ☐ NO

Remarks:

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE DISPOSAL)

A. Procedures describe how packages are received and by whom.

☐ YES ☐ NO

B. Written package opening procedures established and followed **HFS 157.29(6)**

☐ YES ☐ NO

C. If package shows evidence of degradation, monitor for contamination and radiation levels

☐ YES ☐ NO

D. Monitoring of degraded packages performed within time specified **HFS 157.29(6)**

☐ YES ☐ NO

E. Transfer(s) between licensees (including "disposal") performed per **HFS 157.13(10)**

☐ YES ☐ NO

F. Records of receipt/transfer maintained **HFS 157.06(1)**, **HFS 157.13(18)**

☐ YES ☐ NO

G. Transfers within licensee's authorized users or locations performed as required [L/C]

☐ YES ☐ NO

H. Package receipt/distribution activities evaluated for compliance with **HFS 157.29(6)**

☐ YES ☐ NO

Remarks:

11. TRANSPORTATION (Subchapter XIII)

☐ N/A

A. Licensee shipments are:

1. delivered to common carriers

☐ YES ☐ NO ☐ N/A

2. transported in licensee's own private vehicle

☐ YES ☐ NO ☐ N/A

3. no shipments since last audit

☐ YES ☐ NO ☐ N/A

B. Packages

☐ N/A

1. Authorized packages used [49 CFR 173.415 & 173.416(b)]

☐ YES ☐ NO

2. Closed and sealed during transport [49 CFR 173.475(f)]

☐ YES ☐ NO

C. Shipping Papers

☐ N/A

1. Prepared and used [49 CFR 172.200(a)]

☐ YES ☐ NO

2. Proper {Shipping name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of label, T1, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)} [49 CFR 172.200-204]

☐ YES ☐ NO

3. Readily accessible during transport [49 CFR 177.718(e)]

☐ YES ☐ NO

D. Vehicles

1. Cargo blocked and braced [49 CFR 177.842(d)]

☐ YES ☐ NO

2. Placarded, if needed [49 CFR 172.504]

☐ YES ☐ NO

3. Proper overpacks, if used (shipping name, UN Number, labeled, statement indicating that inner package complies with specification package) [49 CFR 173.25]

☐ YES ☐ NO

E. Any incidents reported to DOT [49 CFR 171.15 & 171.16]

☐ YES ☐ NO

Remarks:

12. PERSONNEL RADIATION PROTECTION

A. ALARA considerations are incorporated into the Radiation Protection Program **HFS 157.21**

☐ YES ☐ NO

B. Adequate documentation of determination that unmonitored occupationally

individuals are not likely to receive >10% of allowable limit **HFS 157.25(2)**

☐ YES ☐ NO ☐ N/A

OR

C. External dosimetry provided and required

☐ YES ☐ NO ☐ N/A

1. Supplier _____ Frequency _____

2. Supplier is NVLAP-approved **HFS 157.25(1)**

3. Dosimeters exchanged at required frequency [L/C]

D. Occupational intake monitored and assessed **HFS 157.25(2)**

☐ YES ☐ NO ☐ N/A

E. Reports

☐ N/A

1. Reviewed by _____ Frequency _____

2. Auditor reviewed personnel monitoring records for period
_____ to _____

3. Prior dose determined for individuals likely to receive doses **HFS 157.22(5)**

☐ YES ☐ NO

4. Maximum exposures TEDE Other

5. DHFS Forms or equivalent **HFS 157.31(5) & (7)**

a. "Cumulative Occupational Exposure History" forms are maintained

☐ YES ☐ NO

b. "Occupational Exposure Record for a Monitoring Period" forms are
maintained

☐ YES ☐ NO

6. Worker declared her pregnancy in writing during inspection period (review
records)

☐ YES ☐ NO ☐ N/A

If yes, determine compliance with **HFS 157.22(8)**

☐ YES ☐ NO ☐ N/A

check for records per **HFS 157.31**

☐ YES ☐ NO ☐ N/A

F. Records of exposures, surveys, monitoring, and evaluations maintained per
HFS 157.31

☐ YES ☐ NO

Remarks:

13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

A. Survey instrument:

Serial No.:

Last calibration:

B. Auditor's measurements compared to licensee's

☐ YES ☐ NO

C. Describe the type, location, and results of measurements:

14. NOTIFICATION AND REPORTS

☐ N/A

A. Licensee in compliance with **HFS 157.88** (reports to individuals, public and
occupational, monitored to show compliance)

☐ YES ☐ NO ☐ N/A

B. Licensee in compliance with **HFS 157.32** (theft or loss)

☐ YES ☐ NO ☐ N/A

C. Licensee in compliance with **HFS 157.13(17) and HFS 157.32** (incidents)

☐ YES ☐ NO ☐ N/A

D. Licensee in compliance with **HFS 157.32** (overexposures and high radiation
levels)

☐ YES ☐ NO ☐ N/A

E. Licensee aware of telephone number for DHFS: **(608) 267-4797** from 7:45 a.m.
- 4:30 p.m. and **(608) 258-0099** for after hour radiological emergencies.

☐ YES ☐ NO

15. POSTING AND LABELING

A. "Notice to Employees" is posted per **HFS 157.88**

☐ YES ☐ NO

B. Chapter HFS 157 'Radiation Protection', Subchapters III and X, License and
Operating Procedures are posted, or a notice indicating where documents can
be examined is posted per **HFS 157.88**

☐ YES ☐ NO

C. Emergency procedures are posted per **HFS 157.88**

☐ YES ☐ NO

C. Other posting and labeling per **HFS 157.29 and HFS 157.88**

☐ YES ☐ NO

Remarks:

16. RECORD KEEPING FOR DECOMMISSIONING (if needed) ☐ N/A

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination per **HFS 157.15(7)** ☐ YES ☐ NO

B. Records include all information outlined in **HFS 157.15(7)** ☐ YES ☐ NO

Remarks:

17. INFORMATION NOTICES

A. Receipt of DHFS Information Notices ☐ YES ☐ NO

B. Appropriate action taken in response to Information Notices ☐ YES ☐ NO

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES ☐ N/A

A. Review special license conditions or other issues, and describe findings:

B. Problems/deficiencies identified at licensee facilities other than at audit location:

C. Evaluation of compliance:

19. CONTINUATION OF REPORT ITEMS ☐ N/A

(If more space is needed, use separate sheets and attach to report.)

20. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS ☐ N/A

Note: Briefly state (1) the requirement and (2) how and when violated. Provide recommendations for improvement.

21. EVALUATION OF OTHER FACTORS

A. Senior licensee management is appropriately involved with the radiation safety program and/or Radiation Safety Officer (RSO) oversight ☐ YES ☐ NO

B. RSO has sufficient time to perform his/her radiation safety duties and is not too busy with other assignments ☐ YES ☐ NO

C. Licensee has sufficient staff ☐ YES ☐ NO

Remarks/recommendations:

Appendix M:

Radiation Monitoring Instrument Specifications, Survey Instrument and Air Sampler Calibration Program

Radiation Monitoring Instrument Specifications

The specifications in **Table 9** will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities.

Table 9: Typical Survey Instruments¹ (Instruments used to measure radiological conditions at licensed facilities.)

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-Ray	μR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

¹ Table from The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, 1992 (except for * items).

Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel performing survey instrument calibration; and
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry.
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST);

- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed; and
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of Cs-137 or 7.8×10^2 megabecquerels (21 mCi) of Co-60].

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within $\pm 15\%$ of the conventionally true values for the lower point and $\pm 10\%$ for the upper point;
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10% of the full decade value;
- Meters with a digital display device shall be calibrated the same as meters with a linear scale;
- Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation; and
- The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments

- Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.
- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20% of the conventionally true value.

Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity traceable by documented measurements to a standard certified by National Institutes of Standards and Technology (NIST); and
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration must produce readings within ± 20 per cent of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration records, for all survey instruments, will should indicate the procedure used and the data obtained. The description of the calibration should include:

- The owner or user of the instrument;
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date;
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument;
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument;
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;

- The exposure rate or count rate from a check source, if used; and
- The name of the person who performed the calibration and the date it was performed.

The following information should be attached to the instrument as a calibration sticker or tag:

- For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale;
- The efficiency of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use);
- For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated;
- The date of calibration and the next calibration due date; and
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

In order to assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample must be determined. Accurate determination of the volume of air sampled requires standard, reproducible, and periodic calibration of the air metering devices that are used with air sampling instruments.

The publication entitled '*Air Sampling Instruments*' found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 1989, provides guidance on total air sample volume calibration methods acceptable to DHFS staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (See NRC Regulatory Guide 8.25).
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.

- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument, to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard. Primary standards are usually accurate to within $\pm 1\%$ and secondary standards to within $\pm 2\%$.

The following are significant errors associated with determining the total air volume sampled:

E_C : The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)

E_S : Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)

E_t : The percentage error in measurement of sampling time that should be kept within 1%.

E_V : The most probable value of the cumulative percentage error in the determination of the total air volume sampled.

E_V : can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_V = [E_S^2 + E_C^2 + E_t^2]^{1/2}$$

The most probable value of the cumulative error E_V , in the determination of total volume, should be less than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows: If accuracies of the scale reading, the calibration factor, and sample time are ± 4 , 2, and 1 per cent, respectively, and there are no other significant sources of error, the cumulative error would be:

$$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\% \text{ or approx. } 5\%$$

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

$$V_s = V_1 * (P_1/760) * (273/T_1)$$

Where V_s = volume at standard conditions (760 mm & 0° C)

V_1 = volume measured at conditions P_1 and T_1

T_1 = temperature of V_1 in °K

P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References:

- NRC Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace', which can be accessed at the NRC web site at www.nrc.gov.
- NRC NUREG - 1400, 'Air Sampling in the Workplace', which can be accessed at the NRC website at www.nrc.gov.
- The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien
- ANSI N323A-1997, 'Radiation Protection Instrumentation Test and Calibration.' Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: <http://www.ansi.org>.
- 'Air Sampling Instruments,' American Conference of Governmental Industrial Hygienists, 1987

Appendix N:

Material Receipt and Accountability

Sample Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) shall be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area and re-lock the door.

Radiation Safety Officer (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries will usually be handled by security personnel (or other trained individuals) as described in the above procedures. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

Name _____

Phone _____

For additional information on worker training, see Item 7 <i>‘Training for Individuals Working In or Frequenting Restricted Areas.’</i>
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Sample Procedure for Safely Opening Packages Containing Licensed Materials

For packages received under the specific license, authorized individuals shall implement procedures for opening each package, as follows:

- Wear gloves to prevent hand contamination;
- Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO;
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment does not exceed license possession limits;
- Monitor the external surfaces of a labeled package according to specifications in **Table 5**;
- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Again check that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO;
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash;
- Maintain records of receipt, package survey, and wipe test results; and
- Notify the final carrier and by telephone or facsimile DHFS when removable radioactive surface contamination exceeds the limits of **49 CFR 173.44**; or external radiation levels exceed the limits of **49 CFR 173.44**.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or AU's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the license. All transfers shall be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material shall not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with DHFS, DOT, or U.S. Postal Service rules and regulations, whichever is applicable.

Gifts

On occasion, licensees may be offered or have donated licensed materials by other individuals as gifts (e.g., a retiring medical practitioner donating his cesium needles to the university medical center). All such gifts of radioactive materials must be transferred to the licensee and handled in accordance with DHFS requirements and the conditions of the license. In any case, the RSO should approve the gift prior to the transfer.

Appendix O:

Public Dose

This appendix describes methods for determining radiation doses to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Members of the public include persons who live, work, study, or may be near locations where radioactive material is used or stored and employees whose assigned duties do not include the use of radioactive material but may work in the vicinity where such materials are used or stored.

Doses to Members of the Public	
<p>INCLUDES doses from:</p> <ul style="list-style-type: none"> • Radiation and/or radioactive material released by a licensee • Sources of radiation under the control of a licensee • Air effluents from sources of licensed radioactive materials 	<p>DOES NOT INCLUDE doses from:</p> <ul style="list-style-type: none"> • Sanitary sewerage discharges from licensees • Natural background radiation • Medical administration of radioactive material • Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, but the licensee may control access to these areas for other reasons, such as security.

The licensee may show compliance with the annual dose limit for individual members of the public by:

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem);
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in **Chapter HFS 157 ‘Radiation Protection’, Appendix E Table II**, and if an individual were continuously present in an unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year; and
- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1mSv (10 mrem) TEDE.

In order to perform a dose assessment, licensees should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport, and storage of radioactive material at their facilities. Licensees must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem). These measurements may include:

- Dose rate surveys for radiation exposures from external radiation sources; and
- Measurements of radionuclides in air and water effluent.

The method used to measure dose will depend upon the nature of the radiation source. If the source of radiation is constant, it may be adequate to measure the dose rate and integrate it over time. If the source of radiation differs or changes over time, it may be necessary to perform continuous measurements.

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged when volatile materials are used, such as during iodinations, but the discharge itself is usually not continuous since volatile materials are often used periodically rather than continuously. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

Using a calculation method, the licensee must determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. A conservative calculation should assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see **Table 10**). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If the calculation demonstrates that the public dose limit is exceeded with an occupancy factor of 1, then more realistic assumptions of the individual's occupancy at the points of highest internal and external exposures may be made. The licensee may use the occupancy factors in **Table 10** or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table 10: Standard Occupancy Factors

Occupancy Factor	Description
1	Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas
1/4	Corridors, lounges, elevators using operators, unattended parking lots
1/16	Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic

Records

The licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public until the Commission terminates the license. In general, survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey, the name of the surveyor, the date of the survey, the location of the survey(s)

including a description or drawing of the area surveyed, survey results, and if applicable, the occupancy factors used and justification for their use. In addition, records demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, minimum detectable activity of the system and the estimated uncertainty of measurements.

Appendix P:

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

General Topics for Safe Use of Radioisotopes

Each laboratory or area where radioactive material is used or stored should have general rules, so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used;
- Wear disposable gloves at all times when handling licensed materials;
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area;
- Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used;
- Do not store food, drink or personal effects in areas where licensed material is stored or used (see **Figure 15**);
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored;
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

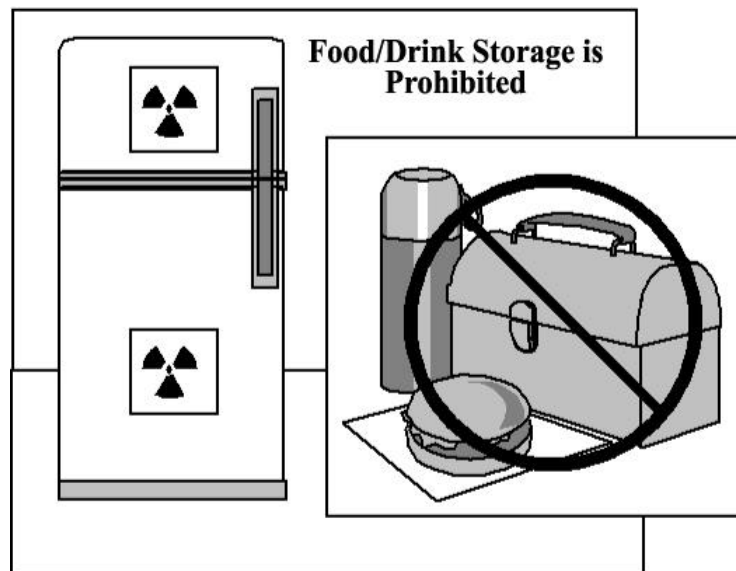


Figure 15: Storage of Food and Drink. Food or drink shall not be stored in refrigerators with radioisotopes.

Radionuclides-specific Procedures

Licensees should develop written procedures for use of different radionuclides so that users know the types of shielding, protective clothing, survey instruments, surveys, and decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq (1 mCi) of iodine-125 or iodine-131, special safety instructions should be provided to users, including the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- Bioassay procedures for individuals working with millicurie quantities of radioiodine;
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine;
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures; and
- Procedures for measuring the concentration of radioiodine effluents from the hoods.

Example 2:

If requesting more than 37 MBq (1 mCi) of phosphorus-32, special safety instructions should be provided to users, including the following:

- The use of low-density plastic shielding in order to keep bremsstrahlung radiation to a minimum;
- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- The use of extremity monitors for procedures that involve one millicurie or more;
- A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures; and
- The use of eye protection for procedures that involve 10 millicuries or more.

Model Procedures for Handling Emergencies

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
 - Disposable gloves;
 - Housekeeping gloves;
 - Disposable lab coats;
 - Disposable head coverings;
 - Disposable shoe covers;
 - Roll of absorbent paper with plastic backing;
 - Masking tape;
 - Plastic trash bags with twist ties;
 - "Radioactive Material" labeling tape;
 - Marking pen;
 - Pre-strung "Radioactive Material" labeling tags;
 - Box of Wipes;
 - Instructions for "Emergency Procedures";
 - Clipboard with a copy of the Radioactive Spill Report Form for the facility;

- Pencil; and
- Appropriate survey instruments including batteries (for survey meters).

Minor Spills of Liquids and Solids

- Instructions to Workers
 - Notify persons in the area that a spill has occurred.
 - Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled).
 - Clean up the spill, wearing disposable gloves and using absorbent paper.
 - Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
 - Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
 - Report the incident to the Radiation Safety Officer (RSO) promptly.
 - Allow no one to return to work in the area unless approved by the RSO.
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Follow up on the decontamination activities and document the results;
 - As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
 - If necessary, notify DHFS.

Major Spills of Liquids and Solids

- Instructions to Workers
 - Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room;
 - Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated;
 - Shield the source only if it can be done without further contamination or significant increase in radiation exposure;
 - Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred;
 - Notify the RSO immediately;
 - Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap;
 - Allow no one to return to work in the area unless approved by the RSO;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
 - Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results;
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin; and
 - If necessary, notify DHFS.

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

- Instructions to Workers
 - Notify all personnel to vacate the room immediately;
 - Shut down ventilation system, if appropriate, to prevent the spread of contamination throughout system and other parts of facility;
 - Vacate the room. Seal the area, if possible;
 - Notify the RSO immediately;
 - Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area;
 - Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO;
 - Promptly report suspected inhalations and ingestions of licensed material to the RSO;
 - Decontaminate the area only when advised and/or supervised by the RSO;
 - Allow no one to return to work in the area unless approved by the RSO;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).
- Reminders to RSO
 - Supervise decontamination activities;
 - Perform air sample surveys in the area before permitting resumption of work with licensed materials;
 - Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc;
 - Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material;
 - Determine cause and corrective actions needed; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident; and
 - If necessary, notify DHFS.

Minor Fires

- Instructions to Workers
 - Immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if other fire hazards or radiation hazards are not present;
 - Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO);
 - Once the fire is out, isolate the area to prevent the spread of possible contamination;
 - Survey all persons involved in combating the fire for possible contamination;
 - Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap;
 - In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area;
 - Allow no one to return to work in the area unless approved by the RSO;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Supervise decontamination activities;
 - If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
 - Consult with fire safety officials to assure that there are no other possibilities of another fire starting;
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident; and
 - If necessary, notify DHFS.

Fires, Explosions, or Major Emergencies

- Instructions to Workers
 - Notify all persons in the area to leave immediately;
 - Notify the fire department;
 - Notify the RSO and other facility safety personnel;
 - Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc;
 - Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples);
 - Allow no one to return to work in the area unless approved by the RSO; and
 - Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
 - Coordinate activities with facility's industrial hygienist or environmental health & safety office, and with local fire department;
 - Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished;
 - Once the fire is extinguished, do not allow the firefighters to enter the radiation area until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas;
 - Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary;
 - Supervise decontamination activities;
 - Consider bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident; and
 - If necessary, notify DHFS.

Copies of emergency procedures must be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.
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Appendix Q:

Radiation Safety Survey Topics

Radiation Safety Survey Topics

This Appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Training

Before allowing an individual to perform surveys, the RSO will ensure that he or she has sufficient training and experience to perform surveys independently.

Academic training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques, and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples; and
- Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv (2.5 mrem/hr) or more (50 mSv/year divided by 2,000 hr/year).
- **HFS 157.23(1)** requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation. While the rule does not specify a specific survey frequency, the licensee is required to ensure that the dose rate limits are not exceeded.

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- After any spill or contamination event;
- When procedures or processes have changed;
- To evaluate the potential contamination of users and the immediate work area, at the end of the day or prior to leaving the area of use, when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly; and

- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified in **Chapter HFS 157 ‘Radiation Protection, Appendix E**, then documented surveys should be performed at least daily in accordance with **HFS 157.31(3)**.

Table 11 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

Table 11: Suggested Contamination Survey Frequency

	< 0.1 ALI	≥ 0.1 ALI < 1.0	≥ 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in **Table 12**.

Table 12: Acceptable Surface Contamination Levels for Equipment

Nuclide ^a	Average ^{b, c}	Maximum ^{b, d}	Removable ^{b, e}
I-125, I-129	1.7 Bq*/100 cm ² (100 dpm/100 cm ²)	5.0 Bq/100 cm ² (300 dpm/100 cm ²)	0.3 Bq/100 cm ² (20 dpm/100 cm ²)
I-126, I-131, I-133, Sr-90	16.7 Bq/100cm ² (1,000 dpm/100 cm ²)	50.0 Bq/100cm ² (3,000 dpm/100 cm ²)	3.3 Bq/100cm ² (200 dpm/100 cm ²)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq*/100 cm ² (5,000 dpm/100 cm ²)	250 Bq/100 cm ² (15,000 dpm /100 cm ²)	16.7 Bq/100 cm ² (1,000 dpm/100 cm ²)

^a Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

^b As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

^c Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

^d The maximum contamination level applies to an area of not more than 100 cm².

^e The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

* 1 Bq = 1 Disintegration per second

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, **Table 12** provides the maximum acceptable residual levels for equipment and **Table 13** provides screening values for building surface contamination. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use, to ensure that they meet these limits.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm² is acceptable to indicate levels of removable contamination.

Table 13: Screening Values for Building Surface Contamination¹

Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm ²)
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Manganese-54	Mn-54	3.2×10^4
Iron-55	Fe-55	4.5×10^6
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Strontium-90	Sr-90	8.7×10^3
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Iridium-192	Ir-192	7.4×10^4

¹ Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using DandD Version 1.

Table 13 does not include screening values for radionuclides that emit alpha particles, or for soil contamination. For such sites, licensees are encouraged to use, in the interim period, site-specific dose assessment based on actual site physical and environmental conditions.

Units are disintegrations per minute per 100 square centimeters (dpm/100 cm²). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in **HFS 157.33(2)**. For radionuclides in a mixture, the "sum of fractions" rule applies; see **Chapter HFS 157 'Radiation Protection, Appendix E, Note 4**. Refer to NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*' for further information on application of the values in this table.

Table 13 was derived using the DandD screening code, Version 1, and its default input parameters. **Table 13** provides criteria which permit licensees to demonstrate compliance with the unrestricted release dose criterion in the License Termination Rule. The values correspond to screening "derived concentration guidelines" for each specific radionuclide based on the methodology described in NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*'. Sites with building surface contamination levels below those listed in **Table 13** would be deemed acceptable for release for

unrestricted use in accordance with the dose criteria in *HFS 157.33(2)*, provided that residual radioactivity has been reduced to ALARA levels. The table is intended for use as criteria to facilitate license termination for many simple routine decommissioning cases without a site-specific dose assessment. For facilities with contamination levels above those in **Table 13**, additional site-specific dose assessments may be necessary, and licensees should refer to NRC NUREG-1727 '*NMSS Decommissioning Standard Review Plan*' regarding acceptable methods for conducting the appropriate dose assessment.

The DandD code can be installed by downloading the self-extracting program file, setup.exe, accessed through the web site: <http://techconf.llnl.gov/radcri/java.html>. NUREG-1727 '*NMSS Decommissioning Standard Review Plan*', NRC NUREG - 1549, 'Decision Methods for Dose Assessment to Comply With Radiological Criteria for License Termination,' dated July 1998, and NRC NUREG/CR - 5512, Vol. #3, 'Residual Radioactive Contamination From Decommissioning, Parameter Analysis,' dated April 25, 1996, can also be accessed through NRC's web site at www.nrc.gov.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed (See **Figure 16**);
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where wipe test was taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background levels; and
- Name of the person making the evaluation and recording the results and date.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

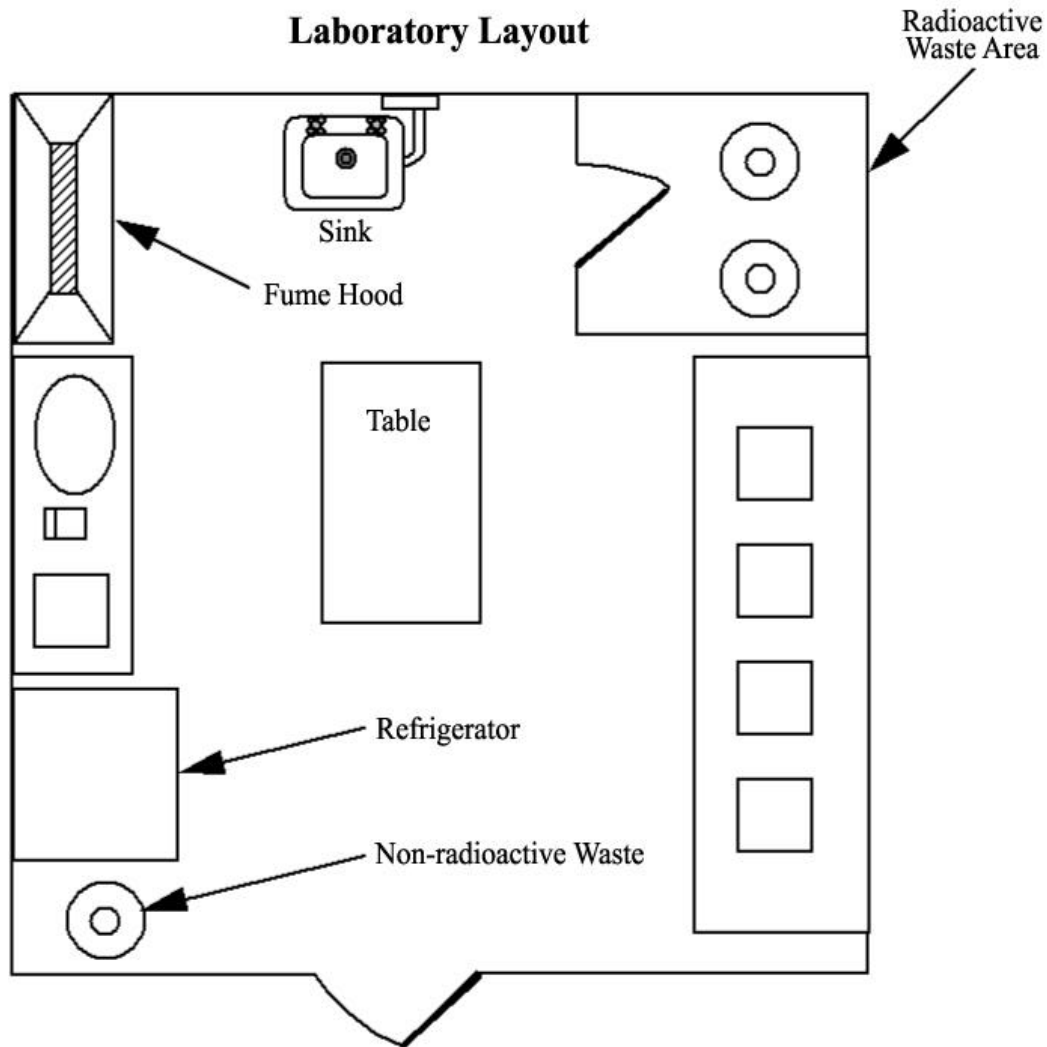


Figure 16: Laboratory Layout. This is an example of a laboratory survey map

Air Monitoring in the Workplace

Air sampling can be used to do the following:

- Determine whether the confinement of radioactive materials is effective;
- Measure airborne radioactive material concentrations in the workplace;
- Estimate worker intakes of radioactive material;
- Determine posting requirements;
- Determine what protective equipment and measures are appropriate; and
- Warn of significantly elevated levels of airborne radioactive materials.

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program may eliminate need for bioassays.

Refer to NRC Regulatory Guide 8.25, Revision 1, '*Air Sampling in the Workplace*' dated June 1992 and NRC NUREG - 1400, '*Air Sampling in the Workplace*' dated September 1993 for further guidance on the air sampling.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

NRC Regulatory Guide 4.20, '*Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors*' dated December 1996, provides guidance on methods acceptable (calculation or COMPLY code) to DHFS for compliance with the constraint on air emissions to the environment.

NRC Regulatory Guide 8.37, '*ALARA Levels for Effluents from Materials Facilities*,' dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur anytime unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent concentrations found on column 1 of Table 2 in **Chapter HFS 157 'Radiation Protection', Appendix E**, whichever is greater.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), '*Document to Sampling Airborne Radioactive Materials in Nuclear Facilities*' and ANSI N42.18, '*Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents*.'

Liquid Effluent Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in **HFS 157.23(1)** and **HFS 157.30(3)**, respectively.

The topic of sanitary sewerage releases is more fully discussed in **Appendix T**.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual;
- Retention and excretion characteristics of the radionuclides;
- Sensitivity of the measurement technique; and
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with **HFS 157.25(2)**, which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc) and the samples collected will vary according to the radionuclide and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program, because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine

measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- The presence of unusually high levels of facial and/or nasal contamination;
- Entry into airborne radioactivity areas without appropriate exposure controls;
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity);
- Known or suspected incidents of a worker ingesting radioactive material;
- Incidents that result in contamination of wounds or other skin absorption; and
- Evidence of damage to or failure of a respiratory protective device.

References: Can be accessed through the NRC's web site at www.nrc.gov and ANSI's web site at www.ansi.org.

- NUREG-1727 '*NMSS Decommissioning Standard Review Plan*'
- Federal Register Notice, 'Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,' Volume 63, Number 222, Page 64132, dated November 18, 1998
- Regulatory Guide 4.20, 'Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors,' dated December 1996
- Regulatory Guide 8.9, Revision 1, 'Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,' dated July 1993
- Regulatory Guide 8.23, Revision 1, 'Radiation Safety Surveys at Medical Institutions,' dated January 1981
- Regulatory Guide 8.25, Revision 1, 'Air Sampling in the Workplace,' dated June 1992
- Regulatory Guide 8.32, 'Criteria for Establishing a Tritium Bioassay Program,' dated July 1988
- Regulatory Guide 8.37, 'ALARA Levels for Effluents from Materials Facilities,' dated July 1993
- NUREG - 1400, 'Air Sampling in the Workplace,' dated September 1993
- NUREG - 1549, 'Decision Methods for Dose Assessment to Comply With Radiological Criteria for License Termination,' dated July 1998
- NUREG/CR - 5512, Vol. #3, 'Residual Radioactive Contamination From Decommissioning, Parameter Analysis,' dated April 25, 1996

- NUREG/CR - 4884, 'Interpretation of Bioassay Measurements,' dated July 1987
- Additional References
- ANSI N13.1 (1969), 'Document to Sampling Airborne Radioactive Materials in Nuclear Facilities,' dated 1991
- ANSI N42.18, 'Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents,' 1991
- NCRP Commentary No. 3, 'Screening Techniques for Determining Compliance with Environmental Standards,' published in January 1989 and the addendum published in October 1989

Appendix R:

Leak Test Procedures

This appendix provides applicants and licensees with leak test procedures and sample calculations for determining activity on a wipe test sample.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at 6 month intervals or as specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclides, and activity.

- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the radionuclides and ensure that its calibration is current.
- Using the selected instrument, count and record background count rate.
- Calculate efficiency.

For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$$

Where: cpm = counts per minute
 std = standard
 bkg = background
 Bq = becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example:
$$\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$$

- Sign and date the list of sources, data and calculations. Retain records for 3 years (*HFS 157.31(3)*).

- If the wipe test activity is 185 Bq (0.005 Ci) or greater, notify the RSO, so that the source can be withdrawn from use, disposed of properly, and DHFS notified in writing within 5 days.

Appendix S:

Transportation

Part 1: Major DOT Regulations

Transportation

The major areas in the DOT regulations that are most relevant for transportation of licensed material shipped as Type A quantities are as follows:

- Hazardous Materials Table: **49 CFR 172.101, App. A**, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides
- Shipping Papers: **49 CFR 172.200-204**: General entries, description, additional description requirements, shipper's certification
- Package Markings: **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling: **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles: **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information: **Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training: **Subpart H, 49 CFR 172.702, 49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements
- Shippers - General Requirements for Shipments and Packaging: **Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A packages, requirements for determining A_1 and A_2 , table of A_1 and A_2 values for radionuclides, radiation level limitations,

contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials

- Radiation Protection Program for Shippers and Carriers: ***Subpart I, 49 CFR 172.801, 49 CFR 172.803, 49 CFR 172.805***: Applicability of the radiation protection program, radiation protection program, record keeping, and notifications
- Carriage by Public Highway - General Information and Regulations: ***Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842***: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Part 2: Sample Shipping Documents, Placards and Labels

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Entries Always Required Unless Excepted	Additional Entries Sometimes Required	Optional Entries
<ul style="list-style-type: none"> The basic description, in sequence: Proper Shipping Name, Hazard Class (7), U.N. Identification Number 24 hour emergency response telephone number Name of shipper Proper page numbering (Page 1 of 4) Except for empty and bulk packages, the total quantity (mass, or volume for liquid), in appropriate units (lbs, mL....) If not special form, chemical and physical form The name of each Radionuclides (95% rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). However, for <u>domestic shipments</u>, the activity may be expressed in terms of customary units only, until 4/1/97. For each labeled package: <ul style="list-style-type: none"> The category of label used; The transport index of each package with a Yellow-II or Yellow-III label Shipper's certification (not required of private carriers) 	<p><u>Materials-Based Requirements:</u></p> <ul style="list-style-type: none"> If hazardous substance, "RQ" as part of the basic description The LSA or SCO group (e.g., LSA-II) "Highway Route Controlled Quantity" as part of the basic description, if HRCQ Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)]) If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982) "Radioactive Material" if not in proper shipping name <p><u>Package-Based Requirements:</u></p> <ul style="list-style-type: none"> Package identification for DOT Type B or NRC certified packages IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473) <p><u>Administrative-Based Requirements:</u></p> <ul style="list-style-type: none"> "Exclusive Use-Shipment" Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-tight or NRC certified LSA (§ 173.427) If a DOT exemption is being used, "DOT-E" followed by the exemption number 	<ul style="list-style-type: none"> The type of packaging (e.g., Type A, Type B, IP-1,) The Technical/chemical name may be included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description) Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used <i>in place of</i> activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered <i>in addition to</i> activity units [see § 172.203(d)(4)] Emergency response hazards and guidance information (§§ 172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§ 172.602(b)]

Some Special Considerations/Exceptions for Shipping Paper Requirements

- Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantity is not a hazardous substance (RQ) or hazardous waste (40 CFR 262)
- Shipping papers must be in the pocket on the left door, or readily visible to person entering driver's compartment and within arm's reach of the driver
- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Markings Always Required Unless Excepted	Additional Markings Sometimes Required	Optional Markings
<p><u>Non-Bulk Packages</u></p> <ul style="list-style-type: none"> Proper shipping name U.N. identification number Name and address of consignor or consignee, <i>unless</i>: <ul style="list-style-type: none"> highway only and no motor carrier transfers, <i>or</i> part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)] 	<p><u>Materials-Based Requirements:</u></p> <ul style="list-style-type: none"> If in excess of 110 lbs (50 kg), Gross Weight If non-bulk <u>liquid</u> package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking] If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name <p><u>Package-Based Requirements:</u></p> <ul style="list-style-type: none"> The package type if Type A or Type B (½" or greater letters) The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)] For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...) If Type B, the trefoil (radiation) symbol per Part 172 App. B [size: outer radius ≥ 20 mm (0.8 in)] For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85) <p><u>Administrative-Based Requirements:</u></p> <ul style="list-style-type: none"> If a DOT exemption is being used, "DOT-E" followed by the exemption number If an export shipment, "USA" in conjunction with the specification markings or certificate markings 	<ul style="list-style-type: none"> "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended Both the name and address of consignor and consignee are recommended Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling
<p><u>Bulk Packages</u> (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment)</p> <ul style="list-style-type: none"> U.N. identification number, on orange, rectangular panel (see §172.332) - some exceptions exist 		

Some Special Considerations/Exceptions for Marking Requirements

- Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the hazmat contents of the package
- Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking
- Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of each nonbulk package must be marked "**Radioactive-LSA**" or "**Radioactive-SCO**," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A₂ quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
- For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a))

Hazard Communications for Class 7 (Radioactive) Materials




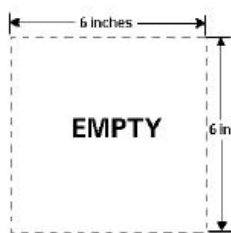
Labeling Packages (49 CFR 172.400-450)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Placement of Radioactive Labels

- Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the package
- For labeling of radioactive materials packages, two labels are required on opposite sides excluding the bottom

Determination of Required Label

Size: <i>Sides:</i> ≥ 100 mm (3.9 in.) <i>Border:</i> 5-6.3 mm (0.2-0.25 in.)				
	49 CFR 172.436	49 CFR 172.438	49 CFR 172.440	49 CFR 172.450
Label	WHITE-I	YELLOW-II	YELLOW-III	EMPTY LABEL
<u>Required when:</u>	Surface radiation level < 0.005 mSv/hr (0.5 mrem/hr)	0.005 mSv/hr (0.5 mrem/hr) < surface radiation level ≤ 0.5 mSv/hr (50 mrem/hr)	0.5 mSv/hr (50 mrem/hr) < surface radiation level ≤ 2 mSv/hr (200 mrem/hr) [Note: 10 mSv/hr (1000 mrem/hr) for exclusive-use closed vehicle (§173.441(b))]	The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to §173.428. It must cover any previous labels, or they must be removed or obliterated.
<u>Or:</u>	TI = 0 [1 meter dose rate < 0.0005 mSv/hr (0.05 mrem/hr)]	TI ≤ 1 [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)]	TI ≤ 10 [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [Note: There is no package TI limit for exclusive-use]	
<u>Notes:</u>	<ul style="list-style-type: none">Any package containing a Highway Route Controlled Quantity (HRCQ) must bear YELLOW-III labelAlthough radiation level transport indices (TIs) are shown above, for fissile material, the TI is typically determined on the basis of criticality control			

Content on Radioactive Labels

- RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):
 - The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
 - The activity in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis. However, for domestic shipments, the activity may be expressed in terms of customary units only, until 4/1/97.
 - The Transport Index (TI) in the supplied box. The TI is entered only on YELLOW-II and YELLOW-III labels

Some Special Considerations/Exceptions for Labeling Requirements

- For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label may not be required on opposite sides, and must not display the hazard class number
- Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classed for that hazard. Hazard communication requirements for the other class are required
- Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use
- The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air [§ 172.402(c)]

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.




Visibility and Display of Radioactive Placard

- Placards are required to be displayed:
 - on four sides of the vehicle
 - visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized)
 - clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins)
 - at least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness
 - upright and on-point such that the words read horizontally
 - in contrast with the background, or have a lined-border which contrasts with the background
 - such that dirt or water from the transport vehicle's wheels will not strike them
 - securely attached or affixed to the vehicle, or in a holder.
- Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

- Placards are required for any vehicle containing package with a RADIOACTIVE Yellow-III label
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A₂ quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel marking with the UN Identification number is not required.
- Placards are required any vehicle containing package with a Highway Route Controlled Quantity (HRCQ). In this case, the placard must be placed in a square background as shown below (see §173.507(a))

Radioactive Placard

<p>Size Specs:</p> <p><i>Sides:</i> ≥ 273 mm (10.8 in.)</p> <p><i>Solid line Inner border:</i> About 12.7 mm (0.5 in.) from edges</p> <p><i>Lettering:</i> ≥ 41 mm (1.6 in.)</p> <p><i>Square for HRCQ:</i> 387mm (15.25 in.) outside length by 25.4 mm (1 in.) thick</p>			
	49 CFR 172.556	IAEA SS 6 (1985) paras. 443-444	See 49 CFR 172.527 AND 556
	RADIOACTIVE PLACARD (Domestic) <i>Base of yellow solid area:</i> 29 ± 5 mm (1.1 ± 0.2 in.) above horizontal centerline	RADIOACTIVE PLACARD (International)	RADIOACTIVE PLACARD FOR HIGHWAY ROUTE CONTROLLED QUANTITY (either domestic or international placard could be in middle)

Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/ SCO exclusive use under §173.427, as above]
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexafluoride (UF₆) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE - YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera)

Minimum Required Packaging For Class 7 (Radioactive) Materials This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials				
Quantity:	< 70 Bq/g (< 0.002 Ci/g)	Limited Quantity (\$173.421)	A ₁ /A ₂ value (\$173.435)	1 rem/hr at 3 m, unshielded (\$173.427)
Non-LSA/SCO:	Excepted	Type A	Type B ³	
Domestic or International LSA/SCO: LSA-I solid, (liquid) ¹ SCO-I	Excepted	IP-I	Type B ³	
LSA-I Liquid LSA-II Solid, (liquid or gas) ¹ (LSA-III) ¹ SCO-II		IP-II	Type B ³	
LSA-II Liquid or Gas LSA-III		IP-III	Type B ³	
Domestic (only) LSA/SCO: LSA-I, II, III; SCO-I, II	Excepted	Strong-tight ²	DOT Spec. 7A Type A	Type B ³ NRC Type A LSA ^{3,4}

- For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive use consignment)
- Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
- Subject to conditions in Certificate, if NRC package
- Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

4. Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (16 CFR 173.52)

Package and Vehicle Radiation Level Limits (49 CFR 173.441) ^A				
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials				
Transport Vehicle Use:	Non-Exclusive	Exclusive		
Transport Vehicle Type:	Open or Closed	Open (flat-bed)	Open w/Enclosure ^B	Closed
Package (or freight container) Limits:				
External Surface	2 mSv/hr (200 mrem/hr)	2 mSv/hr (200 mrem/hr)	10 mSv/hr (1000 mrem/hr)	10 mSv/hr (1000 mrem/hr)
Transport Index (TI) ^C	10	no limit		
Roadway or Railway Vehicle (or freight container) Limits:				
Any point on the outer surface	N/A	N/A	N/A	2 mSv/hr (200 mrem/hr)
Vertical planes projected from outer edges		2 mSv/hr (200 mrem/hr)	2 mSv/hr (200 mrem/hr)	N/A
Top of...		load: (200 mrem/hr)	enclosure: 2 mSv/hr (200 mrem/hr)	vehicle: 2 mSv/hr (200 mrem/hr)
2 meters from. . .		vertical planes: 0.1 mSv/hr (10 mrem/hr)	vertical planes: 0.1 mSv/hr (10 mrem/hr)	outer lateral surfaces: 0.1 mSv/hr (10 mrem/hr)
Underside	N/A ^D	2 mSv/hr (200 mrem/hr)		
Occupied position		0.02 mSv/hr (2 mrem/hr) ^E		
Sum of package TI's		no limit ^F		

A. The limits in this table do not apply to excepted packages - see 49 CFR 173.421-426

B. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures

C. For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1m (3.3 feet) from the exterior package surface, in millirem/hour

D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages

E. Does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I

F. Some fissile shipments may have combined conveyance TI limit of 100 - see 10 CFR 71.59 and 49 CFR 173.457

Package and Vehicle Contamination Limits (49 CFR 173.443)		
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials		
NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm ² Sufficient measurements must be taken in the appropriate locations to yield representative assessments		
&(means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters " means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)		
The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11	General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)	
	&(: 0.4 Bq/cm ² = 40 Bq/100 cm ² = 1x10 ⁻⁵ :Ci/cm ² = 2200 dpm/100 cm ²	
	" : 0.04 Bq/cm ² = 4 Bq/100 cm ² = 1x10 ⁻⁶ :Ci/cm ² = 220 dpm/100 cm ²	
The following exceptions and deviations from the above basic limits exist:		
Deviation from Basic Limits	Regulation 49 CFR §§	Applicable Location and Conditions Which must Be Met:
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	On any external surface of a package in an exclusive use shipment, during transport including end of transport. Conditions include: (1) Contamination levels at beginning of transport must be below the basic limits. (2) Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination.
10 times the basic limits	173.443(d) Also see 177.843 (highway)	On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include: (1) A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). (2) Exterior of vehicle must be conspicuously stenciled, " For Radioactive Materials Use Only " in letters at least 76 mm (3 inches) high, on both sides. (3) Vehicle must be kept closed except when loading and unloading.
100 times the basic limits	173.428	Internal contamination limit for excepted package-empty packaging, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: (1) The basic contamination limits (above) apply to external surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5) Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.
In addition, after any incident involving spillage, breakage, or suspected contamination, the modal-specific DOT regulations (§177.861(a), highway; §174.750(a), railway; and §175.700(b), air) specify that vehicles, buildings, areas, or equipment have "no significant removable surface contamination," before being returned to service or routinely occupied. The carrier must also notify offer or at the earliest practicable moment after incident.		

Example Certificate Enclosed In/or on Package, Included with the Packing List or Otherwise Forwarded with the Package)

<p>This package conforms to the conditions, and limitations specified in 49 CFR 173.424 for radioactive material, excepted package-instruments or articles, UN2910.</p> <p>_____</p> <p>(Signed) Radiation Safety Officer</p>

Appendix T:

Waste Management Procedures

General Guidelines

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal in ordinary (non-radioactive) waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- Remind workers that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.
- Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
- Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

Procedure for Disposal by Decay-in-storage (DIS)

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
- Short-lived waste should be segregated from long-lived waste (half-life greater than 120 days) at the source.
- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.
- Liquid and solid wastes must be stored separately.
- When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
- The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container may be transferred to the DIS area.

- The contents of the container should be allowed to decay for at least 10 half-lives of the longest-lived radioisotope in the container.
- Prior to disposal as ordinary trash, each container should be monitored as follows:
 - Check the radiation detection survey meter for proper operation;
 - Survey the contents of each container in a low background area;
 - Remove any shielding from around the container;
 - Monitor all surfaces of the container;
 - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e., surface readings are indistinguishable from background; and
 - If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.
- If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

Procedure for Disposal of Liquids Into Sanitary Sewerage

- Confirm that sewerage system is a public system, not a private sewerage system, septic system, or leach field.
- Confirm that the liquid waste being discharged is soluble or biological material that is readily dispersible in water.
- Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in **Chapter HFS 157 ‘Radiation Protection’, Appendix E**.
- Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in **HFS 157.30(3)** and **Chapter HFS 157 ‘Radiation Protection’, Appendix E**.
- Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks, toilets or release points.
- Discharge liquid waste slowly to with water running from the faucet to dilute it.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Prior to leaving the area, decontaminate all areas or surfaces, if found to be contaminated.
- Maintain records of each radioisotope and its quantity and concentration that is released into the sanitary sewer system.